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INTERIM CLINICAL STUDY REPORT - BNT162-01

Version:	3.0	**Date of this report:**	20 MAR 2021
Sponsor:	BioNTech SE 55131 Mainz, Germany	**Date of previous reports**	23 SEP 2020 (ver. 1.0) 28 NOV 2020 (ver. 2.0)

Title of study	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
Study number	BNT162-01
Protocol version	Version 9.0 (dated 05 OCT 2020); the version valid at the 23 OCT 2020 reactogenicity, safety, disposition, and immunogenicity data cut-off
Study design	Multi-site, Phase I/II, dose-escalation and expansion study
Regulatory identifiers	EudraCT no.: 2020-001038-36; ClinicalTrials.gov: NCT04380701; WHO UTN: U1111-1249-4220
Investigational medicinal products (IMPs)	BNT162: SARS-CoV-2 - RNA lipid nanoparticle (RNA-LNP) vaccines utilizing different RNA formats, i.e., BNT162b1 and BNT162b2
Indication	Protection against COVID-19 caused by the SARS-CoV-2 virus
Phase of development	I/II
Sponsor signatories	Elizabeth Adams, MD, Senior Medical Director, BioNTech US, Inc. Stefan Liebscher, Responsible Statistician
Coordinating investigator	Dr. Dr. med. Armin Schultz, CRS Clinical Research Services Mannheim GmbH, Germany
Study sites	Sites in Berlin and Mannheim, Germany. For further details of the study sites and site personnel, see Appendix 16.1.4.
Study period	Study start / end date: 23 APR 2020 / Ongoing Early study termination: Not applicable
Type of report	Interim report (the BNT162-01 study is clinically ongoing; see the below notes)

This clinical study is still clinically ongoing. This third interim clinical study report (CSR) summarizes reactogenicity and safety data available for BNT162b1 and BNT162b2 collected up until Visit 8 (the first follow-up visit at ~63 d after the second dose) for dose-escalation and dose-expansion cohorts (dose groups) in Part A of this study, therefore this CSR only describes the study conduct relevant for these dose groups. This CSR differs from the second interim CSR in that additional cell-mediated immunity (CMI) data were added for a small number of participants that received 10, 20, and 30 µg BNT162b2 using research samples collected at Visit 8 (63 d post-Dose 2) and Visit 9 (162 d post-Dose 2).

The respective data cut-off dates are: reactogenicity, safety, disposition, and immunogenicity data (23 OCT 2020); T-cell response data (ELISpot data) data (02 MAR 2021); intracellular cytokine staining (ICS) data (17 NOV 2020 for BNT162b1 and 02 MAR 2021 for BNT162b2).

The data from this study, together with data from other sources including the study BNT162-02/C4591001, were used to select the BNT162 vaccine and dose level for further study in the Phase II/III evaluation of efficacy.

Data not included here will be provided in later interim reports and/or the final CSR, which will include data for the other IMPs under investigation in this study (i.e., BNT162a1 and BNT162c2).

Good Clinical Practice (GCP) statement: The study was conducted according to GCP guidelines, the applicable local laws, and in accordance with the ethical principles that have their origins in the Declaration of Helsinki.

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4 LIST OF ABBREVIATIONS, TERMS, AND NOTES FOR THE READER

Abbreviation/Term	Explanation
≤ (a number)	Less than or equal to (a number)
≥	Equal to or greater than (a number)
~	Approximately
AE	Adverse event
BMI	Body mass index
BNT162b	BNT162 RNA-LNP vaccine utilizing nucleoside modified mRNA (data for the variants BNT162b1 and BNT162b2 are reported in this CSR)
CMI	Cell-mediated immunity/immune response
COVID-19	Coronavirus disease 2019
CRF	Case report form
CRO	Contract research organization
CRP	C-reactive protein
CSR	Clinical study report
d	Day(s)
Day	Study day
Dose group	Groups of study participants who receive the same IMP at the same dose level and who belong to the same age group, i.e., younger participants or older participants.
ECG	Electrocardiogram
ELISpot	Enzyme-linked immunosorbent-spot
EoT	End of treatment
EudraCT	European Union drug regulating authorities clinical trials database
GCLP	Good clinical laboratory practice
GCP	Good clinical practice
GMC	Geometric mean concentration
GMFI	Geometric means fold increase
GMT	Geometric mean titer
h	Hour(s)
HCS	Human convalescent serum
HIV	Human Immunodeficiency Virus
HLA	Human leukocyte antigen
ICF	Informed consent form
ICS	Intracellular cytokine staining
IEC	Independent ethics committee
IFN	Interferon
IgG	Immunoglobulin G
IL	Interleukin
IM	Intramuscular(ly)
IMM	Immunogenicity Set
IMP	Investigational medicinal product; in this study, BNT162 vaccines

Abbreviation/Term	Explanation
LOD	Limit of detection
MedDRA®	Medical Dictionary for Regulatory Activities
min	Minute(s)
modRNA	Nucleoside modified messenger RNA
mRNA	Messenger RNA
NCT	(Clinicaltrials.gov) National clinical trial number
NE	Note estimable
Neutralizing GMTs	Virus (SARS-CoV-2) neutralizing antibody geometric mean titers
Older participants	Participants aged 56 to 85 yrs
P/B	Dose 1/Dose 2: a dosing regimen, comprising a priming immunization (Dose 1) and a Dose 2 immunization (Dose 2)
PBMC	Peripheral blood mononuclear cell
PT	Preferred term
RBD	Receptor binding domain
Reactogenicity events	Solicited local reactions or systemic reactions
R&D	Research & Development
RNA	Ribonucleic acid
RNA-LNP	RNA lipid nanoparticle
SAE	Serious adverse event
SAF	Safety Set
SAFB	Safety Dose 2 set (Safety Boost Set)
SAP	Statistical analysis plan
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SD	Single dose (also referred to as “single priming dose” or “single immunization”)
SoA	Schedule of activities
SOC	System organ class
SOP(s)	Standard operating procedure(s)
S protein	SARS-CoV-2 sp ke protein
SRC	Safety Review Committee
Participant	Also referred to as “study participant” or “trial subject” or “subject”. Participants who signed an informed consent form, i.e., who gave informed consent
TEAE	Treatment-emergent adverse event
TEAE-SI	Treatment-emergent adverse event of special interest; TEAE-SI are defined as: Enhanced respiratory disease or flu-like symptomatology not resolved after 7 d or with symptom kinetics that are inconsistent with a relationship to RNA immunization.
TESAE	Treatment-emergent serious adverse event
Th1	T helper type 1
Th2	T helper type 2
TMF	Trial master file
Study participant	Also referred to in some documentation as “participant” or “trial subject” or “subject”. Participants who signed an ICF, i.e., who gave informed consent.
US	United States (of America)
UTN	(WHO) Universal trial number
VNT	Virus neutralization test

Abbreviation/Term	Explanation
WHO	World Health Organization
wk(s)	Week(s)
WOCBP	Women of childbearing potential
Younger participants	Participants aged 18 to 55 yrs
yr(s)	Year(s)

Notes for the reader

To harmonize data reporting across the different BNT162 clinical studies, the following terminology was harmonized in this interim study report. The protocol, SAP, Section 14 tables/figures, and Section 16 listings use the original BioNTech terminology:

- Boost (dose) = Dose 2
- Cohort = dose group
- Immunization / immunized = dosing / dosed
- Prime (dose) = Dose 1
- Safety Dose 2 set = Safety boost set
- Subject = participant
- Trial = study
- Vaccination / vaccinated = dosing / dosed
- Vaccine = IMP

5 ETHICS

5.1 Independent ethics committee (IEC)

The protocol (see Appendix 16.1.1.1) and the informed consent form (ICF) (see Appendix 16.1.1.2) were reviewed and approved by the responsible IEC. The consulted IEC, including the name of the committee chair, is provided in Appendix 16.1.3.

This clinical study is still clinically ongoing. At the reactogenicity, safety, disposition, and immunogenicity data cut-off for this CSR (23 OCT 2020), a total of six protocol amendments were issued, submitted to the IEC, and were approved where applicable (for details, see the Protocol Amendment History provided in Appendix 16.1.1.3).

5.2 Ethical conduct of the study and regulatory approval

The study was conducted according to GCP guidelines, the applicable local laws, and in accordance with the ethical principles that have their origins in the Declaration of Helsinki.

The competent authority, the German Paul-Ehrlich-Institut, approved the study as required by national regulations.

5.3 Participant information and consent

The participation of the participants and the investigation of their eligibility were subject to informed consent. Only participants who were able and willing to consent freely to participate after receiving detailed information both verbally and in writing were eligible for enrollment.

Before the start of any study-related examination, an investigator or investigator's delegate informed the participants about the nature, importance, implications, and risks of the study. The participants were informed about the study treatments, the method of administration, blood sampling, rules of conduct, and any restrictions that applied. Possible effects and side effects of the study treatments were discussed. The extent of the examinations to be performed and the invasive and noninvasive investigation methods were explained. The participants were given the opportunity to ask questions concerning any and all aspects of the study. All participants were informed that participation was voluntary and that they could cease participation at any time without necessarily giving a reason and without any penalty or loss of benefits to which they were entitled. They had to be able to understand the full implications of their decision to participate in the study.

Local ICFs were drawn up in German before the start of the study. A copy of the local ICFs were supplied to the IEC for approval.

All study participants signed the local ICF valid at the time of their enrollment as proof of consent. Study participants were given a copy of the signed ICFs.

The ICFs supplied with this report (Appendix 16.1.1.2) are English translations of the local ICFs (one each for the trial, additional blood draws for immunogenicity monitoring, and additional blood draws for human leukocyte antigen [HLA] typing).

6 INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

This study initially was sponsored by BioNTech RNA Pharmaceutical GmbH and conducted clinically by CRS Clinical Research Services Mannheim GmbH (the clinical CRO) at CRS sites in Berlin and Mannheim Germany. On the 04 DEC 2020, i.e., after the reactogenicity, safety, disposition, and immunogenicity data cut-off for this report, the study sponsor was changed to BioNTech SE.

Medical and clinical monitoring of this study was conducted by the sponsor or its designated representatives.

The study was conducted by CRS investigators under the direction of the sponsor. The investigators were responsible for adhering to the study procedures described in the protocol, for keeping records of the study interventions, and for ensuring accurate completion of the CRFs and data collection tools supplied by the sponsor.

6.1 Medical investigators and investigative sites

A list of the investigators that includes their affiliation and their role in the study is provided in Appendix 16.1.4. The documentation, e.g., curriculum vitae, of the qualifications of the investigators and other site personnel is held in the trial master file (TMF). The signature of the coordinating investigator is provided in Appendix 16.1.5.

6.2 External suppliers and CROs

A list of external suppliers and CROs is provided in Appendix 16.1.4.

6.3 Sponsor’s personnel

A list of persons employed by the sponsor whose participation materially affected the conduct of the study is provided in Appendix 16.1.4. Documentation of the qualifications of these personnel is held in the sponsor’s records. Signatures of the sponsor signatories are provided in Appendix 16.1.5.

6.4 Insurance

No-fault insurance coverage for the study participants was arranged with insurance companies in accordance with local requirements. Relevant documentation is maintained in the TMF. Before the start of the study, the study participants were informed by the investigator about the existence of this insurance coverage.

6.5 Committees

This study has a Safety Review Committee (SRC) to monitor study participant safety during the study. SRC tasks include confirming IMP doses before use, advising regarding appropriate safety measures (e.g., prolongation of post-dose on site observation periods), monitoring (and if required stopping) study participant dosing within a dose group or stopping administration of Dose 2. For further details of SRC tasks and membership, see Protocol Section 10.1.5. Documentation of the data reviewed and outcomes are filed in the TMF.

7 INTRODUCTION

7.1 Context

SARS-CoV-2 infections and the caused disease COVID-19 are increasing every day and spreading globally, affecting more and more countries, and COVID-19 was declared pandemic by the World Health Organization (WHO) on March 11th, 2020. There is therefore a need for vaccines or antiviral drugs to treat these infections or its caused disease COVID-19.

BioNTech has developed a technology platform of RNA-based vaccines which enables the rapid development of vaccines against emerging viral diseases (for more details, see Protocol Section 2.1). This technology platform is especially attractive because it has the ability to deliver high numbers of vaccine doses rapidly in a single production campaign.

This study investigates the potential safety and immunogenicity of prophylactic RNA-based BNT162 vaccines against SARS-CoV-2; this study includes the first in human administration of four BNT162 vaccines. Further details are provided in Protocol Section 2.1.

This interim CSR only reports study conduct and results for dose-escalation and dose-expansion dose groups for BNT162b1 and BNT162b2 in healthy younger participants (aged 18 to 55 yrs) and older participants (aged 56 to 85 yrs).

7.2 Background to the IMPs BNT162b1 and BNT162b2

The nucleoside modified messenger RNA (modRNA) drug substance for BNT162b1 and BNT162b2 are single-stranded 5′-capped RNAs that are translated upon entering the cell. In addition to the sequence encoding the SARS-CoV-2 antigen (i.e., open reading frame), each modRNA contains common structural elements optimized for high efficacy of the RNA translation. For further details about BNT162b1 and BNT162b2, see Table 1.

Table 1: Characteristics of BNT162b1 and BNT162b2

RNA platform	Vaccine (product code)	Encoded antigen
modRNA	BNT162b1	Secreted variant of the SARS-CoV-2 RBD with the T4 fibritin-derived “foldon” trimerization domain
	BNT162b2	Full-length SARS-CoV-2 spike protein bearing mutations preserving neutralization-sensitive sites

modRNA = nucleoside modified ribonucleic acid; RBD = receptor binding domain.

7.3 Rationale

For the scientific rationale for the study, for the study design, and for the used doses, see Protocol Sections 2.2, 4.2, and 4.3, respectively.

7.4 Regulations and agreements with regulatory authorities

No specific agreements with regulatory authorities were applicable to Part A of this study.

8 STUDY OBJECTIVES AND ENDPOINTS

Only objectives and endpoints applicable for BNT162b1 and BNT162b2 are reflected in the following tabular summary of study objectives and endpoints.

Objectives	Endpoints [a]
Primary objective	
(All dose groups) To describe the safety and tolerability profiles of prophylactic BNT162 vaccines in healthy adults after Dose 1 only or after Dose 1 and Dose 2.	• Solicited local reactions at the injection site (pain, tenderness, erythema/redness, induration/swelling) recorded up to 7 d after each dose (study days 8 and 29). • Solicited systemic reactions (nausea, vomiting, diarrhea, headache, fatigue, myalgia, arthralgia, chills, loss of appetite, malaise, and fever) recorded up to 7 d after each dose (study days 8 and 29). • The proportion of subjects with at least one unsolicited TEAE occurring up to 28 d after Dose 1 (study day 29) and 28 d after Dose 2 (study day 50).
Secondary objectives	
(All dose groups) To describe the immune response in healthy adults after Dose 1 only or after Dose 1 and Dose 2 measured by a functional antibody titer, e.g., VNT or an equivalent assay available by the time of study conduct.	As compared to baseline at 7 and 21 d after Dose 1 (study days 8 and 22) and at 7, 14 [b], 21, 28, 63, and 162 d after Dose 2 (study days 5 to 9): • Functional antibody responses (titers). • Fold increase in functional antibody titers. • Number of subjects with seroconversion defined as a minimum of 4-fold increase of functional antibody titers as compared to baseline.
Exploratory objectives	
(All dose groups) To describe the immune response in healthy adults after Dose 1 only or after Dose 1 and Dose 2 measured by an antibody binding assay, e.g., ELISA or an equivalent assay available by the time of study conduct.	As compared to baseline at 7 and 21 d after Dose 1 (study days 8 and 22) and at 7, 14 [b], 21, 28, 63, and 162 d after Dose 2 (study days 8 to 184). • Antibody responses measured (concentrations/titers). • Fold increase in antibody (concentrations/titers). • Number of subjects with seroconversion defined as a minimum of 4-fold increase of antibody concentrations/titers. Note: The assessment days were extended to include assessments at 63 d after Dose 2.
(All dose groups) To describe the CMI responses, e.g., by ELISpot and ICS.	• At baseline and at 28 d after Dose 1 (study day 29): CMI responses measured. Note: For BNT162b2, the assessment days were extended to include assessment at study day 85 (i.e., 63 d post-Dose 2) and study day 184 (i.e., 162 d post-Dose 2).

a) The given days are approximate; the respective schedule of activities defines assessment windows.

b) Only cohorts starting dosing with IMP after approval of protocol version 09.

Note: To harmonize data reporting across BNT162 clinical studies, several terms, e.g., the terms "prime" and "boost" were replaced with "Dose 1" and "Dose 2", respectively. For further details, see the Section 4 of this report.

9 INVESTIGATIONAL PLAN

Descriptions of any deviations from the protocol, any changes in the conduct of the study, and any changes in the planned analyses are given in Section 9.12.

9.1 Overall study design and plan – description

The study design is described in detail in Protocol Section 4.1.

An overall description of the study is presented in the flow diagram in Figure 1.

A schedule of events is given in Table 2.

A sample CRF is included in Appendix 16.1.2.

9.2 Discussion of study design

A discussion of the study design is provided in Protocol Section 4.2.

9.3 Selection of study population

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. Study participants were selected from this pool of volunteers according to inclusion and exclusion criteria given in Sections 9.4 and 9.5.

Prospective approval of protocol deviations to recruitment and enrollment criteria, also known as protocol waivers or exemptions, were not permitted.

9.4 Inclusion criteria Part A

Volunteers were only enrolled in the study if they met all of the following criteria:

1. Have given informed consent by signing the ICF before initiation of any study-specific procedures.
2. They must be willing and able to comply with scheduled visits, treatment schedule, laboratory tests, lifestyle restrictions (e.g., to practice social distancing and to follow good practices to reduce their chances of being infected or spreading COVID-19), and other requirements of the study.
3. They must be able to understand and follow study-related instructions.
4. For younger participant dose groups, volunteers must be aged 18 to 55 yrs, have a BMI over 19 kg/m^2 and under 30 kg/m^2, and weigh at least 50 kg at Visit 0.

   OR

   For older adult dose groups, volunteers must be aged 56 to 85 yrs, have a BMI over 19 kg/m^2 and under 30 kg/m^2, and weigh at least 50 kg at Visit 0.
5. They must be healthy, in the clinical judgment of the investigator, based on medical history, physical examination, 12-lead ECG, vital signs (systolic/diastolic blood

pressure, pulse rate, body temperature, respiratory rate), and clinical laboratory tests (blood chemistry, hematology, and urine chemistry) at Visit 0.

Note: Healthy volunteers with pre-existing stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 wks before enrollment, can be included.

6. Women of childbearing potential (WOCBP) must have a negative beta-human chorionic gonadotropin urine test at Visit 0 and Visit 1. Women that are postmenopausal or permanently sterilized will be considered as not having reproductive potential.
7. WOCBP must agree to practice a highly effective form of contraception during the study, starting after Visit 0 and continuously until 60 d after receiving the last IMP dose. WOCBP must agree to require their male partners to use condoms during sexual contact (unless male partners are sterilized or infertile).
8. WOCBP must confirm that they practiced at least one highly effective form of contraception for the 14 d prior to Visit 0.
9. WOCBP must agree not to donate eggs (ova, oocytes) for the purposes of assisted reproduction during study, starting after Visit 0 and continuously until 60 d after receiving the last IMP dose.
10. Men who are sexually active with a WOCBP and have not had a vasectomy must agree to practice a highly effective form of contraception with their female partner of childbearing potential during the study, starting after Visit 0 and continuously until 60 d after receiving the last IMP dose.
11. Men must be willing to refrain from sperm donation, starting after Visit 0 and continuously until 60 d after receiving the last IMP dose.
12. They must have confirmation of their health insurance coverage prior to Visit 0.
13. They must agree to not be vaccinated during the study, starting after Visit 0 and continuously until 28 d after receiving the last IMP dose.

9.5 Exclusion criteria Part A

Volunteers were excluded from the study if they meet or present any of the following criteria:

1. Have had any acute illness, as determined by the investigator, with or without fever, within 72 h prior to the first immunization. An acute illness which is nearly resolved with only minor residual symptoms remaining is allowable if, in the opinion of the investigator, the residual symptoms will not compromise their wellbeing if they participate as study participants in the study, or that could prevent, limit, or confound the protocol-specified assessments.
2. Are breastfeeding on the day of Visit 0 or who plan to breastfeed during the study, starting after Visit 0 and continuously until at least 90 d after receiving the last IMP dose.

3. Have a known allergy, hypersensitivity, or intolerance to the planned IMP including any excipients of the IMP.
4. Had any medical condition or any major surgery (e.g., requiring general anesthesia) within the past 5 yrs which, in the opinion of the investigator, could compromise their wellbeing if they participate as study participants in the study, or that could prevent, limit, or confound the protocol-specified assessments.
5. Have any surgery planned during the study, starting after Visit 0 and continuously until at least 90 d after receiving the last IMP dose.
6. Had any chronic use (more than 21 continuous days) of any systemic medications, including immunosuppressant's or other immune-modifying drugs, within the 6 months prior to Visit 0 unless in the opinion of the investigator, the medication would not prevent, limit, or confound the protocol-specified assessments or could compromise participant safety.
   Note: Healthy participants with pre-existing stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 wks before enrollment, can be included.
7. Received any vaccination within the 28 d prior to Visit 0.
8. Had administration of any immunoglobulins and/or any blood products within the 3 months prior to Visit 0.
9. Had administration of another investigational medicinal product including vaccines within 60 d or five half-lives (whichever is longer), prior to Visit 0.
10. Have a known history or a positive test of any of HIV 1 or 2, Hepatitis B, or Hepatitis C, within the 30 d prior to Visit 0.
11. Have a positive PCR-based test for SARS-CoV-2 within the 30 d prior to Visit 1.
12. Have a positive drugs of abuse (for amphetamines, benzodiazepines, barbiturates, cocaine, cannabinoids, opiates, methadone, methamphetamines, phencyclidine, and tricyclic antidepressants) result at Visit 0 or Visit 1.
13. Have a positive breath alcohol test at Visit 0 or Visit 1.
14. Previously participated in an investigational study involving lipid nanoparticles.
15. Are subject to exclusion periods from other investigational studies or simultaneous participation in another clinical study. When entering the follow-up phase, i.e., after completing the EoT visit, subjects are allowed to participate in other clinical trials not investigating COVID-19 vaccines or treatments.
16. Have any affiliation with the study site (e.g., are close relative of the investigator or dependent person, such as an employee or student of the study site).
17. Have a history (within the past 5 yrs) of substance abuse or known medical, psychological, or social conditions which, in the opinion of the investigator, could compromise their wellbeing if they participate as study participants in the study, or that could prevent, limit, or confound the protocol-specified assessments.
18. Have a history of hypersensitivity or serious reactions to previous vaccinations.

19. Have a history of Guillain-Barré syndrome within 6 wks following a previous vaccination.
20. Have a history of narcolepsy.
21. Have history of alcohol abuse or drug addiction within 1 yr before Visit 0.
22. Have a history of or suspected immunosuppressive condition, acquired or congenital, as determined by medical history and/or physical examination at Visit 0.
23. Have any abnormality or permanent body art (e.g., tattoo) that, in the opinion of the investigator, would obstruct the ability to observe local reactions at the injection site.
24. Have had any blood loss >450 mL, e.g., due to donation of blood or blood products or injury, within the 7 d prior to Visit 0 or plan to donate blood during the study, starting after Visit 0 and continuously until at least 7 d after receiving the last IMP dose.
25. Symptoms of COVID-19, e.g., respiratory symptoms, fever, cough, shortness of breath and breathing difficulties.
26. Have had contact with persons diagnosed with COVID-19 or who tested positive for SARS-CoV-2 by any diagnostic test within the 30 d prior to Visit 1.
27. Are soldiers, are in detention, are CRO or sponsor staff or their family members.
28. Regular receipt of inhaled/nebulized corticosteroids.
29. For older adults only: Have a condition known to put them at high risk for severe COVID-19, including those with any of the following risk factors:
    - Hypertension
    - Diabetes mellitus
    - Chronic obstructive pulmonary disease
    - Asthma
    - Chronic liver disease
    - Known Stage 3 or worse chronic kidney disease (glomerular filtration rate <60 mL/min/1.73 m^2)
    - Serious heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
    - Sickle cell disease
    - Cancer
    - Are immune compromised due to stem cell or organ-transplantation with significant medical complications such as acute or chronic graft rejection or graft versus host disease requiring intensive immunosuppressive treatment, transplant failure or infectious complications or other conditions that would be considered a contraindication for vaccination

- Are immune compromised due to HIV infection with a CD4+ count of < 200 x 106 /L at screening or significant medical complications such as opportunistic infections, malignant complications (e.g., lymphoma, Kaposi sarcoma), other organ manifestations consistent with advanced AIDS or other conditions that would be considered a contraindication for vaccination
- Resident in a long-term facility
- Current vaping or smoking (occasional smoking is acceptable)
- History of chronic smoking within the prior year

9.6 Removal of participants from the study, study assessments or IMP

Criteria for study participant discontinuation from the study or IMP are listed in Protocol Section 7. The handling of study participant discontinuation from the study or IMP is described in Protocol Section 7.

9.7 Treatments

9.7.1 Treatments administered

The administration of study treatments is described in detail in Protocol Section 6.

9.7.2 Investigational medicinal products

Name:	BNT162 vaccines - Antiviral RNA vaccines for active immunization against COVID-19.
IMP and dose levels:	Younger participants aged 18 to 55 yrs: BNT162b1: 1 µg, 3 µg, 10 µg, 20 µg, 30 µg, 50 µg, and 60 µg. BNT162b2: 1 µg, 3 µg, 10 µg, 20 µg, 30 µg. Older participants aged 56 to 85 yrs: BNT162b1: 10 µg, 20 µg, and 30 µg. BNT162b2: 10 µg, 20 µg, and 30 µg.
Dosing regimen:	Two injections ~21 d apart. Injection volumes were up to 0.5 mL.
Dosing route:	IM; upper arm, musculus deltoideus. Use of the same arm for both doses was allowed. The non-dominant arm was preferred.
Batch Nr.:	BNT162b1: E220195-0001L, E220195-0004L, E220195-0014L. BNT162b2: E220195-0004L, E220195-0017L, E220195-0018L.

Packaging and labeling of the IMPs are described in the Pharmacy Manual and the connected appendix provided in Appendix 16.1.1.4.

Instructions for delivery, storage, and disposal of IMP are described in the Pharmacy Manual and the connected appendix provided in Appendix 16.1.1.4.

A listing connecting the participants receiving each batch is provided in Appendix 16.1.6.

9.7.3 Method of assignment to dose groups (allocation)

Study participants were not assigned to the study dose groups according to a randomization plan. Dose groups are groups of study participants who receive the same IMP at the same dose level and who belong to the same age group, i.e., younger participants or older participants.

9.7.4 Selection of doses in the study

The rationale for the selection of doses for this study is provided in Protocol Section 4.3. During the study, the SRC is required to confirm or adapt the acceptability of the planned IMP dose before use.

9.7.5 Selection and timing of dose for each participant

Study participants received IMP as described in Protocol Section 6.1.

9.7.6 Blinding and unblinding

Not applicable because this is an open-label study.

9.7.7 Prior and concomitant medication

Allowed and forbidden concomitant medications are given in Protocol Section 6.5.

9.7.8 Treatment compliance

The IMP was administered by a physician as described in Protocol Section 6.1.

Drug accountability requirements are specified in Protocol Section 6.2.

9.8 Genetic, biomarker, immunogenicity, and safety variables

9.8.1 Study assessments and schedule of events

An overall description of the study is presented in the flow diagram in Figure 1.

A schedule of events is given in Table 2.

A detailed description of the study procedures is provided in Protocol Section 8.

Table 2: Schedule of study procedures and assessments for BNT162b1 and BNT162b2

Procedure / Assessment	Visit 0	Visit 1 Pre-dose	Visit 1 (Post-) dosing	Visit 2 at 24±2h	Phone call at 48±2h	Visit 3	Visit 4 Pre-dose	Visit 4 Dosing & Post-dose	Phone call at 48±2h	Visit 5	Visit 5a	Visit 6	Visit 7 (EoT Visit)	Visit 8 (FU Visit)	Visit 9 (FU Visit)
Day [h]	**-30 to 0**	**1**	**1**	**2**		**8**	**22**	**22**		**29**	**36 [q]**	**43**	**50 [r]**	**85**	**184**
Days to last dose [h]		**0**	**0**			**7**	**21**	**0**		**7**	**14**	**21**	**28**	**63**	**162**
Informed consent	X														
Inclusion/exclusion criteria	X	X (review)													
Medical history	X	X (update)													
Physical examination incl. height	X	X [a]		X [a]		X [a]	X [a]			X [a]		X [a]	X [a]		
Vital signs, body weight [c]	X	X	X [b]	X		X	X	X [b]		X		X	X	X	X
12-lead ECG	X	X													
Urine pregnancy test for WOCBP	X	X					X								
Urine drugs of abuse screen [d]	X	X													
Alcohol breath test	X	X													
Urine collection for clinical laboratory [e]	X	X		X		X				X			X		
Blood draw for clinical laboratory (15 mL) [f]	X	X		X		X				X			X		
Blood draw for viral screening [g]	X (5 mL)														
Blood draw for SARS-CoV-2 testing [k]	X (2.6 mL)														

Procedure / Assessment	Visit 0	Visit 1 Pre-dose	Visit 1 (Post-) dosing	Visit 2 at 24±2h	Phone call at 48±2h	Visit 3	Visit 4 Pre-dose	Visit 4 Dosing & Post-dose	Phone call at 48±2h	Visit 5	Visit 5a	Visit 6	Visit 7 (EoT Visit)	Visit 8 (FU Visit)	Visit 9 (FU Visit)
Day [h]	-30 to 0	1	1	2		8	22	22		29	36 [q]	43	50 [r]	85	184
Days to last dose [h]		0	0			7	21	0		7	14	21	28	63	162
Oral swipe for SARS-CoV-2 testing		X [m]													
Allocation to IMP		X													
Immunization			X [l]					X							
Blood draw for immunogenicity (10 mL) [n]		X				X	X			X	X	X	X	X	X
Blood draw for HLA			X (4 mL EDTA-blood) [p]												
Blood draw for CMI (100 mL) [n, o]		X								X					
Blood draw for research												X (≤100 mL)		X (≤50 mL)	X (≤50 mL)
Subject hotline availability	Start	=>	=>	=>		=>	=>	=>		=>	=>	=>	=>	=>	End
Issue participant diaries		X		X		X	X			X		X	X		
Collect participant diaries				X	X [i]	X	X			X		X	X	X	
Record AEs since last visit		X		X		X	X			X	X	X	X	X [j]	X [j]
Local reaction assessment/ systemic events			X [b]	X		X	X	X [b]		X		X	X		
Concomitant medication	X	X		X		X	X			X		X	X		
Subject wel being questioning					X [i]				X [i]						

a) Brief (symptom-directed) physical examination; no height measurement.
b) At 1, 3, and 6 h (±15 min) after immunization.
c) Vital signs: systolic/diastolic blood pressure, pulse rate, respiratory rate, and body temperature; body weight only at Visit 0.
[d)] Urine screening for drugs of abuse (amphetamines, benzodiazepines, barbiturates, cocaine, cannabinoids, opiates, methadone, methamphetamines, phencyclidine, tricyclic antidepressants).
e) Dipstick urine analysis. Microscopic urinalysis: if warranted by dipstick results.
f) Clinical laboratory tests: chemistry and hematology. Only in women who are not WOCBP (to confirm postmenopausal status): follicle stimulating hormone at Visit 0.
g) Viral screening for human immunodeficiency virus (HIV) 1 or 2, hepatitis B, hepatitis C.
h) Flexibility for visit days: Visit 3 Day 8±1 d; Visit 4 Day 22±2 d; Visit 5 Day 29±3 d; Visit 6 Day 43±4 d; Visit 7 Day 50±4 d; Visit 8 Day 85±7 d; Visit 9 Day 184±9d.
i) Only for the first six participants per group. Questioning on and documentation of AEs as well as systemic and local reactions, the latter in case of upcoming dose decision meetings.
j) Only IMP-related AEs and any SAEs.
k) Blood draw for anti-SARS-CoV-2 antibodies (samples will be stored until a test is commercially available).
l) For Dose Groups 1 and 8, immunization with at least 1 h intervals between participants for the first six participants and then with of at least 30 min intervals for the remaining 6 participants. For all other dose groups, immunization with at least 15 min intervals between participants and for the boost injections.
m) Oral swipe for SARS-CoV-2 testing either on Day -1 or at the Visit 1 on Day 1.
n) The listed blood draw days may be adapted if justified by the collected data. Leftover blood after completion of the immunogenicity assessments may be used for additional analyses as described in Protocol Section 8.7 (Genetics) and/or Protocol Section 8.8 (Biomarkers).
o) For participants who have given consent, one aliquot of the blood sample drawn for analysis of CMI may be used for HLA typing to allow additional analysis of T-cell receptor repertoire and / or phenotypic characterization of T cells specific to vaccine-encoded antigens.
p) If HLA typing using the blood sample collected with Lithium Heparin is not conclusive, EDTA-blood will be drawn for HLA testing.
q) Only dose groups with dose 1 after approval of protocol amendment 06.
r) When entering the follow-up phase, i.e., after completing the EoT visit, participants are allowed to participate in other clinical studies not investigating COVID-19 vaccines or treatments.

Notes: If the boost dose was not administered or if study participants permanently discontinued from IMP administration, participants were to complete all assessments planned for that visit and for the EoT Visit as listed in the SoA; The additional Visit 5a added by protocol amendment 06 will only applied for participants who gave consent.

Abbreviations: AE = adverse event; CMI = cell-mediated immune testing; D or d = day; ECG = electrocardiogram; EDTA = ethylenediamine tetraacetic acid; EoT = end of treatment (Visit); FU = follow-up (visit); h = hour(s); HLA = human leukocyte antigen; Day 0 = one day before Day 1; IMP = investigational medicinal product; min = minute(s); WOCBP = women of childbearing potential.

9.8.2 Demography and other baseline characteristics

The demographic and other baseline characteristics collected in this study were: age (in years/months), gender (male/female), ethnic group, and medical history information.

The collection of demographic and other baseline characteristics data is described in Protocol Section 10.12.

9.8.3 Genetics, biomarkers, and immunogenicity assessments

Details of the genetic assessments are provided in Protocol Section 8.7.

Details of the biomarker assessments are provided in Protocol Section 8.8.

Details of the immunogenicity (antibody response) assessments are provided in Protocol Section 8.9.

9.8.4 Safety assessments

The safety data collected in this study were: physical examinations, vital signs, ECG, clinical laboratory tests, drugs of abuse screens, tests for alcohol use, viral screening, participant diaries, assessment of local reactions, SAR-CoV-2 testing, participant hotline, participant wellbeing questioning, assessment of systemic reactions, and AE reporting.

The collection of safety data in the study is described in Protocol Section 8.3 (for AEs and SAEs) and Protocol Section 8.2 (all other safety assessments).

9.8.5 Appropriateness of measurements

The safety assessments, which included the assessments of AEs and local/systemic reactivity in support of the primary study objective, were performed using standard procedures.

9.9 Data quality assurance

9.9.1 Site selection, clinical monitoring, and site performance

The accuracy and reliability of the study data were assured by the selection of qualified investigators and appropriate study sites, review of protocol procedures with the investigator and associated personnel prior to the study, and by periodic monitoring visits by the sponsor or sponsor's representative.

An investigators' meeting took place before the study started. All investigators not present at that meeting were informed either by the CRO or by the sponsor.

Written instructions were provided for the collection, preparation, and shipment of samples. Electronic CRFs were used in the study. Instructions for completing the CRFs were provided and reviewed with study personnel prior to the start of the study. Training had to be successfully completed before access to the system was allowed.

All CRF entries, corrections, and alterations were made by the investigator or other authorized site personnel. The investigator verified if data entries in the CRFs were

accurate and correct. The CRFs were reviewed for accuracy and completeness by the sponsor and sponsor's representative and any discrepancies were resolved with the investigator or designees as appropriate. For details, see Protocol Sections 10.11.1 and 10.11.3.

9.9.2 Assessment of CRO performance

The CRO for the study conduct was qualified according to the sponsor's standard operating procedures (SOPs) in cooperation with the sponsor's quality assurance department. Before the study started, the CRO's SOPs were reviewed. The conduct of the study was performed according to the CRO's SOPs. The sponsor performed CRO activities oversight.

9.9.3 Data quality control procedures

Study data not recorded in the CRF were transferred electronically using a secure method to the data management center at predefined intervals during the study in a data structure agreed with the sponsor.

Data verification was performed on the data in the database using computerized checks looking for missing data, inconsistencies, and incorrect values. A manual review of the data was also performed. If necessary, queries were generated and transmitted to the site. The investigator was requested to confirm or make corrections or enter additional or missing data as required. Further data quality control measures were defined in the data validation plan, which are filed in the TMF.

In addition, a reconciliation of reportable adverse events between the global drug safety and clinical databases as well as a reconciliation of other non-CRF data were performed.

9.9.4 Data documentation and archiving

The handling of CRFs, genetic data, source data, the investigator's site file, and the TMF are described in Protocol Section 10.11.

9.9.5 Audit procedures

The Mannheim study site was inspected by relevant authorities (the "Regierungspräsidium Karlsruhe" and Paul-Ehrlich-Institut) on 07 OCT 2020, 08 OCT 2020, and 22 OCT 2020.

9.10 Statistical methods and determination of sample size

9.10.1 Statistical and analytical plans

9.10.1.1 General

The statistical planning and analysis of the study was performed at the statistical CRO under supervision of the sponsor's delegate.

The first participant was enrolled in the study on 23 APR 2020.

The study statistical analysis plan (SAP) can be found in Appendix 16.1.9. The SAP version 4.0 was approved on 18 NOV 2020 prior to database use to generate tables, figures, and listings, used in this CSR. The SAP includes a more technical and detailed description of the statistical analyses described in this section. Any deviations from the planned analyses described in the SAP are described and justified in this CSR.

Additional analyses or analyses not performed strictly according to the protocol and forming part of this CSR are described in full in the SAP and are summarized in Section 9.12.2.

In Part A, no formal statistical hypothesis was tested.

Statistical analyses were performed by the sponsor or a designated CRO. All statistical analyses were carried out using SAS®, Version 9.4, and/or other statistical software as required.

In general, data were summarized by dose groups and dose groups were combined as appropriate. Continuous variables were summarized by dose group using the following descriptive statistics: number of participants (n), mean, SD, median, minimum and maximum. Categorical variables were summarized by dose group presenting absolute and relative frequencies (n and %) of participants in each category. Baseline was defined as last available value prior to first dose of IMP.

9.10.1.2 Participant populations (analysis sets)

Analysis set	Description
Screened set	All participants who signed informed consent.
Safety set (SAF)	All participants who received at least one dose of IMP.
Immunogenicity set (IMM)	All participants who received at least one dose of IMP and have at least one post-baseline functional antibody titer immunogenicity assessment.
Dose 1 + 7 d completer set	All participants who are included in the SAF and received the Dose 1 and who were in the study at least up to Day 7 (inclusive) after Dose 1.
Dose 1 to Dose 2 or Dose 1 + 28 d completer set	All participants who are included in the SAF and received Dose 1 and who either received also the Dose 2 or who were in the study at least up to Day 28 (inclusive) after Dose 1.
Dose 2 + 7 d completer set	All participants who are included in the SAF and received the Dose 2 and who were in the study at least up to Day 7 (inclusive) after Dose 2.
Dose 2 + 28 d completer set	All participants who are included in the SAF and received the Dose 2 and who were in the study at least up to Day 28 (inclusive) after Dose 2.
Dose 1 or Dose 2 + 28 d completer set	All participants who are included in the SAF and received Dose 1 and who either received also the Dose 2 and were in the study at least up to Day 28 (inclusive) after Dose 2 or who did not receive the Dose 2 and were in the study at least up to Day 28 (inclusive) after Dose 1. Note to completer sets: Participants were not in the study up to a certain day if, for example, they dropped out before or did not complete the time interval due to the cut-off of a snapshot analysis.

Analysis set	Description
Safety Dose 2 set (Safety Boost Set, [SAFB])	All participants who received 2 doses of IMP (i.e., both Dose 1 and Dose 2).

Note: In all analysis sets, participants were assigned to the groups (i.e., vaccine type and cohort) according to the actual treatment they received ("as treated"). Several terms were aligned with terminology in other BNT162 studies, to harmonize data reporting across BNT162 clinical studies. For further details, see the Section 4 of this report.

9.10.1.3 Demographics and other baseline characteristics

Details of the analysis of demographics and other baseline characteristics are provided in SAP Section 6.3.

9.10.1.4 Statistical methodology

Details of the statistical methodologies are provided in SAP Section 6.

9.10.1.5 Primary endpoint analysis

The primary endpoints are defined in Section 8.

Details of the primary analyses are provided in SAP Section 6.4.

All AEs were coded using the Medical Dictionary for Regulatory Activities (MedDRA®) coding system (version 23.0) to get a SOC and PT for each AE.

All TEAEs were summarized using the Safety Set.

In general, AEs were analyzed by dose group (i.e., by IMP and dose level) and for each dose, i.e.:

- Day 1 to 8 (7 d after Dose 1)
- Day 1 to 22 (pre-Dose 2) (21 d after Dose 1)
- Day 21 (post-Dose 2) to 28 (7 d after Dose 2)
- Day 21 (post-Dose 2) to 50 (28 d after Dose 2)

Additionally, AEs were summarized for all dose levels combined for each type.

For each analysis, the number and percentage of participants reporting at least one AE were summarized by PT nested within SOC for each of the following AE types using the Safety Set:

- Any AE
- Any AE excluding AEs based on solicited reporting via participant diaries
- Related AE
- Grade ≥3 AE
- Related Grade ≥3 AE
- Any SAE
- Related SAE

- TEAE-SI

Moreover, the number and percentage of participants with any AE were summarized by worst grade by PT nested within SOC.

Local reactions and systemic reactions were 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".

For each dose, the number and percentage of participants reporting at least one local reaction or systemic reaction (i.e., solicited data collected using participant diaries) were summarized for each of the following types using the Safety Set:

- Any local reactions or systemic reactions
- Grade ≥3 local reactions or systemic reactions

Moreover, the number and percentage of participants reporting at least one local reaction were summarized by worst grade using the Safety Set.

9.10.1.6 Secondary endpoint analysis

The secondary endpoints are defined in Section 8.

Details of the secondary analyses are provided in SAP Section 6.5.

All secondary analysis endpoints will be summarized by group (i.e., by vaccine type and cohort) and all cohorts combined for each type (cohort-total). The binary secondary endpoints were summarized by dose group presenting absolute and relative frequencies (n and %) of participants in each category for each assessment. The continuous secondary endpoints are summarized by dose group using summary statistics.

9.10.1.7 Analysis of other safety analyses

Details of the analysis of other safety variables are provided in SAP Section 6.

Clinical laboratory

The clinical laboratory parameters summarized and assessed are listed in Protocol Section 10.2.

Clinical laboratory parameters at each time point and change from baseline to each post-baseline time point were summarized using descriptive summary statistics for each parameter by dose group.

Shift tables from baseline to worst intensity grade are provided for each laboratory parameter by dose group.

Additionally, the occurrence of clinically significant abnormal laboratory results within a study participant were analyzed using descriptive summary statistics for each parameter and visit by dose group.

Abnormal laboratory results were 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".

Laboratory parameter results were listed along with the normal ranges. Values that are below or above the normal ranges were flagged.

Vital signs

The vital sign parameters to be summarized and assessed are given in Protocol Section 8.2.2.

Vital sign parameters at each time point and change from baseline to each post-baseline time point were summarized using descriptive summary statistics for each parameter by dose group.

ECG

ECG parameters to be summarized and assessed are given in Protocol Section 8.2.3. ECGs were judged by the investigator as clinically significant (yes/no).

Further safety data

Physical examination, drugs of abuse, alcohol use, viral screening and the SARS-CoV-2 testing was listed.

Compliance

IMP compliance will be summarized by group (i.e., by vaccine type and cohort) and cohort-total. Drug exposure will be listed.

9.10.1.8 Interim analysis

In Part A, no formal interim statistical analysis was performed. However, preliminary analyses based on all data collected until a predefined data cut-off date (snapshot analyses) could be performed for each cohort once subjects within a cohort have been followed up for at least 7 days following the dose. An analysis update is planned once all subjects have completed Visit 10.

9.10.2 Sample size rationale

No formal sample size calculations were performed.

For Part A, the inclusion of 12 participants per dose group was considered to be adequate for a safety assessment of each IMP per dose level. The probability to observe a particular TEAE with incidence of 15% at least once in 12 participants per dose group is 85.8%.

9.11 Data available for this interim report

This third interim CSR summarizes reactogenicity and safety data available for BNT162b1 and BNT162b2 collected up until Visit 8 (the first follow-up visit at ~63 d after the second dose) for dose-escalation and dose-expansion dose groups in Part A of this study, therefore this CSR only describes the study conduct relevant for these dose groups. This CSR differs from the second interim CSR in that additional CMI data were added for a small number of participants that received 10, 20, and 30 µg BNT162b2 using research samples collected at Visit 8 (63 d post-Dose 2) and Visit 9 (162 d post-Dose 2).

The respective data cut-off dates are: reactogenicity, safety, disposition, and immunogenicity data (23 OCT 2020); T-cell response data (ELISpot data) data (02 MAR 2021); ICS data (17 NOV 2020 for BNT162b1) and (02 MAR 2021 for BNT162b2).

The data reported here, together with data from other sources including the study BNT162-02/C4591001 (NCT04368728), was used to select the BNT162 vaccine and dose level for further study in the Phase II/III evaluation of efficacy.

Data not included here will be provided in later interim reports and/or the final CSR, which will include data for the other IMPs under investigation in this study (i.e., BNT162a1 and BNT162c2).

See the following table for a summary of the reactogenicity and safety available data at the cut-off date for this report.

IMP	Dose	Age group	23 OCT 2020 data cut-off
BNT162b1	1 µg	18 to 55 yrs	Dose 2 + 28 d (Visit 7, i.e., Day 50)
	3 µg	18 to 55 yrs	Dose 2 + 28 d (Visit 7, i.e., Day 50)
	10 µg	18 to 55 yrs	Dose 2 + 28 d (Visit 7, i.e., Day 50)
	30 µg	18 to 55 yrs	Dose 2 + 28 d (Visit 7, i.e., Day 50)
	50 µg	18 to 55 yrs	Dose 2 + 28 d (Visit 7, i.e., Day 50)
	60 µg	18 to 55 yrs	Dose 2 + 28 d (Visit 7, i.e., Day 50)
	20 µg	18 to 55 yrs	Dose 2 + 28 d (Visit 7, i.e., Day 50)
	10 µg	56 to 85 yrs	Dose 2 + 28 d (Visit 7, i.e., Day 50)
	20 µg	56 to 85 yrs	Dose 2 + 7 d (Visit 5, i.e., Day 29)
	30 µg	56 to 85 yrs	Dose 2 + 7 d (Visit 5, i.e., Day 29)
BNT162b2	1 µg	18 to 55 yrs	Dose 2 + 28 d (Visit 7, i.e., Day 50)
	3 µg	18 to 55 yrs	Dose 2 + 28 d (Visit 7, i.e., Day 50)
	10 µg	18 to 55 yrs	Dose 2 + 28 d (Visit 7, i.e., Day 50)
	20 µg	18 to 55 yrs	Dose 2 + 28 d (Visit 7, i.e., Day 50)
	30 µg	18 to 55 yrs	Dose 2 + 28 d (Visit 7, i.e., Day 50)
	10 µg	56 to 85yrs	Dose 2 + 7 d (Visit 5, i.e., Day 29)
	20 µg	56 to 85yrs	Dose 2 + 7 d (Visit 5, i.e., Day 29)
	30 µg	56 to 85yrs	Dose 2 + 7 d (Visit 5, i.e., Day 29)

yrs = years.

Immunogenicity data for baseline up until Visit 8 (63 d post-Dose 2) is summarized in this interim CSR.

CMI data for baseline up until Visit 9 (162 d post-Dose 2); this includes CMI data for Visit 8 (63 d post-Dose 2) and Visit 9 (162 d post-Dose 2) obtained by repurposing research samples for CMI assessment is summarized in this interim CSR.

9.12 Changes in the conduct of the study or planned analyses

9.12.1 Changes in the conduct of the study

9.12.1.1 Amendments to the protocol

Changes made to the protocol using the protocol amendments are described in detail in the document Protocol Amendment History provided in Appendix 16.1.1.3.

9.12.1.2 Discrepancies between protocol and the CRF

There were no discrepancies between the protocol and the CRF.

9.12.1.3 Other changes in the conduct of the study

In a small number of participants receiving 10, 20, and 30 µg BNT162b2, CMI was assessed using research samples collected at Visit 8 (63 d post-Dose 2) and Visit 9 (162 d post-Dose 2).

Dosing of participants with the second 60 µg BNT162b1 dose was not performed. After 12 participants had received Dose 1, the SRC decided not to administer Dose 2 to these participants.

There were no other changes in the conduct of the study considered by the sponsor to either impact the study objectives or to have compromised participant safety.

9.12.2 Changes in the planned analyses

There was one change in the analyses as described in the SAP.

The SAP states that functional antibody response data from VisMederi Srl will be used for the analysis of functional antibody responses; this is correct for the main analysis that will be reported in the final CSR. However, for this interim CSR, functional antibody response data from Pfizer Inc. (Pearl River, NY, US) / University of Texas Medical Branch, Galveston, TX, US) are reported (for details see Report R-20-0253). This was done to enable comparison of data from this study with data from the clinical study BNT162-02/C4591001 (ClinicalTrials.gov NCT04368728) which reports functional antibody response data from Pfizer Inc. (Pearl River, NY, US) / University of Texas Medical Branch, Galveston, TX, US).

10 STUDY PARTICIPANTS

This report covers study conduct and results for BNT162b1 and BNT162b2 in healthy younger participants (aged 18 to 55 yrs) and older participants (aged 56 to 85 yrs).

10.1 Disposition of participants

10.1.1 BNT162b1

The disposition of the 84 younger participants is given in Figure 2. This disposition relates to the reactogenicity, safety, disposition, and immunogenicity data (data cut-off 23 OCT 2020).

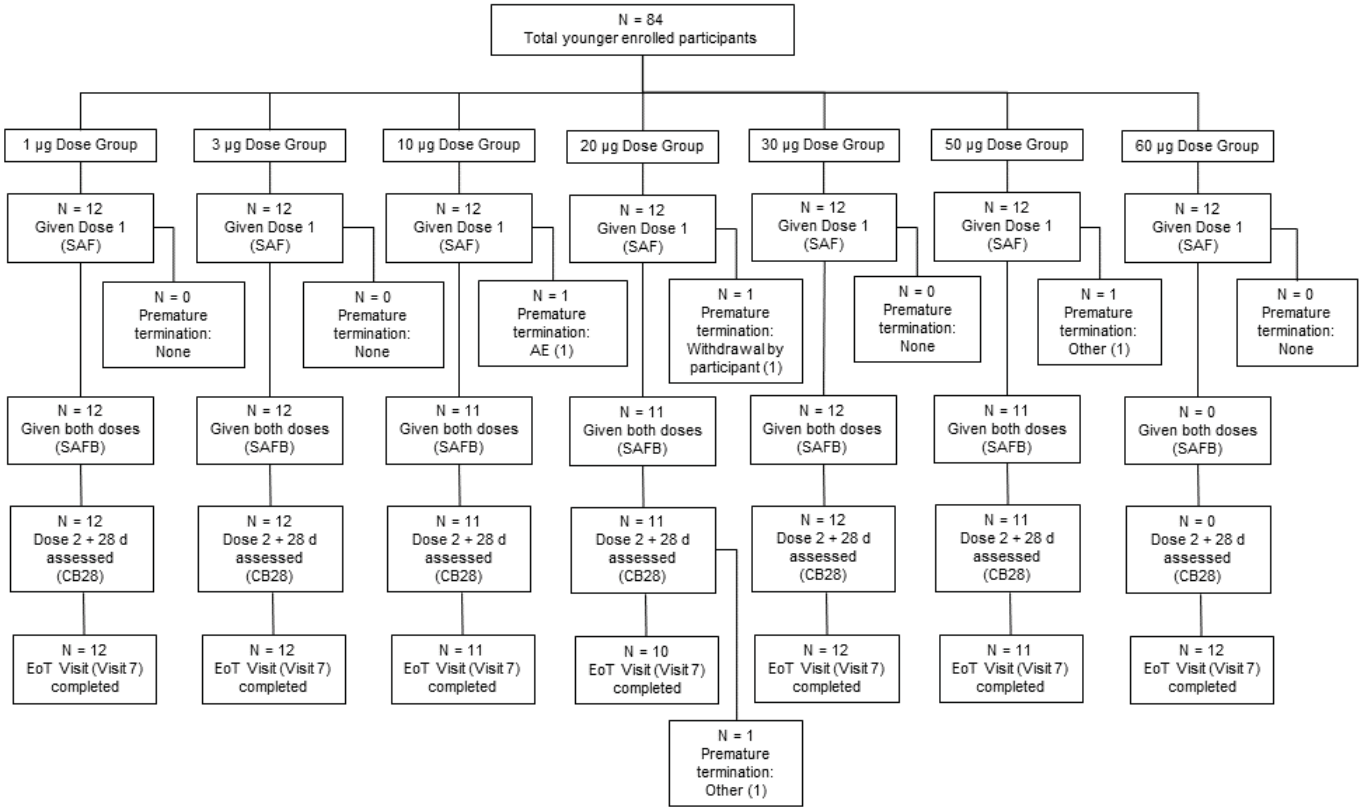

Figure 2: Disposition of younger participants – BNT162b1

AE = adverse event; EoT Visit (Visit 7) completed = end of treatment visit completed (as recorded in the database at the 23 OCT 2020 data cut-off date); N = number of participants; SAF = safety set; SAFB = safety boost set; Dose 2 + 28 d assessed (CB28) = Dose 2 + 28 d completer set.

Source: Based on data from Table 14.1-2-1, Table 14.1-3.1-1, and Listing 16.2.1-1-1.

The disposition of the 36 older participants is given in Figure 3.

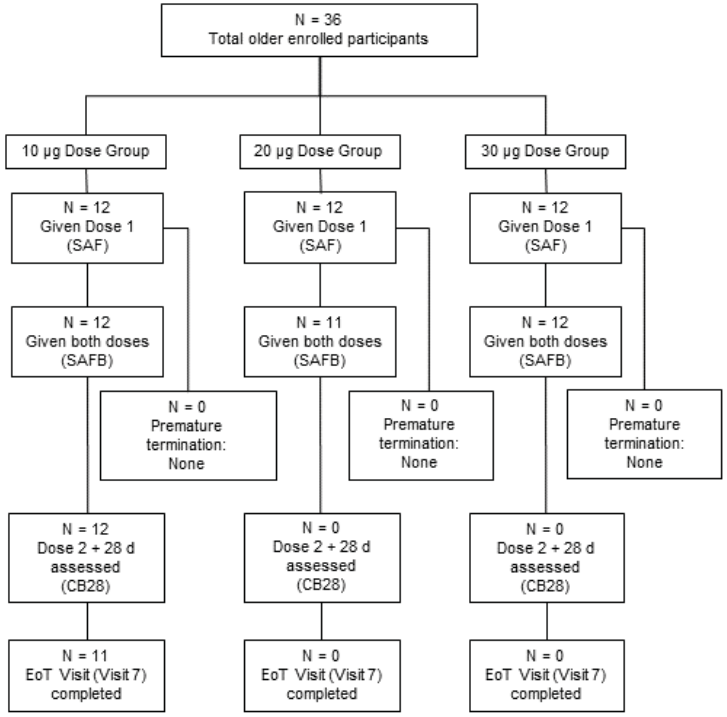

Figure 3: Disposition of older participants – BNT162b1

EoT Visit (Visit 7) completed = end of treatment visit completed (as recorded in the database at the 23 OCT 2020 data cut-off date); N = number of participants; SAF = safety set; SAFB = safety boost set; Dose 2 + 28 d assessed (CB28) = Dose 2 + 28 d completer set.

Source: Based on data from Table 14.1-2-1, Table 14.1-3.1-1, and Listing 16.2.1-1-1.

A total of 84 younger participants and 36 older participants (in total 120 participants) were enrolled in BNT162b1 dose groups in Part A of this study. At the data cut-off (23 OCT 2020), the Dose 2 + 28 d completer set (CB28) comprised 69 of 84 younger and 12 of 36 older participants (Table 14.1-2-1), and 80 of 84 younger and 11 of 36 older participants had completed Visit 7 (the EoT Visit) (Listing 16.2.1-1-1).

Four younger participants discontinued prematurely from the study (Table 14.1-3.1-1).

One younger participant discontinued prematurely from the study due to AEs after Dose 1 (Participant 10010 in the 10 µg dose group); these AEs were assessed as not related to the IMP by the investigator; for details see Section 12.6.1.

Three younger participants discontinued prematurely for reasons not due to AEs (in the 20 µg dose group: Participant 10178 [other/private reason; after Dose 2], Participant 10182 [withdrawal by participant; after Dose 1]; Participant 10050 [other/private reason; after Dose 1]) in the 50 µg dose group.

Note that Participant 10178 in the 20 µg dose group discontinued prematurely later than 28 d after Dose 2 but did not complete the EoT visit.

Twelve younger participants (10066, 10075, 10076, 10078, 10083, 10084, 10085, 10089, 10093, 10096, 10103, and 10104) in the BNT162b1 60 µg dose group did not receive Dose 2 due to a SRC decision but completed their EoT visits. Although the observations after Dose 1 at 60 µg did not raise safety concerns, the high level of inter-individual differences and the limitations of the data available at that time were considered as not enough to allow administration of Dose 2.

For further details, see Listing 16.2.1-1-1 and Listing 16.2.1-3-1.

10.1.2 BNT162b2

The disposition of the 60 younger participants is given in Figure 4. This disposition relates to the reactogenicity, safety, disposition, and immunogenicity data (data cut-off 23 OCT 2020).

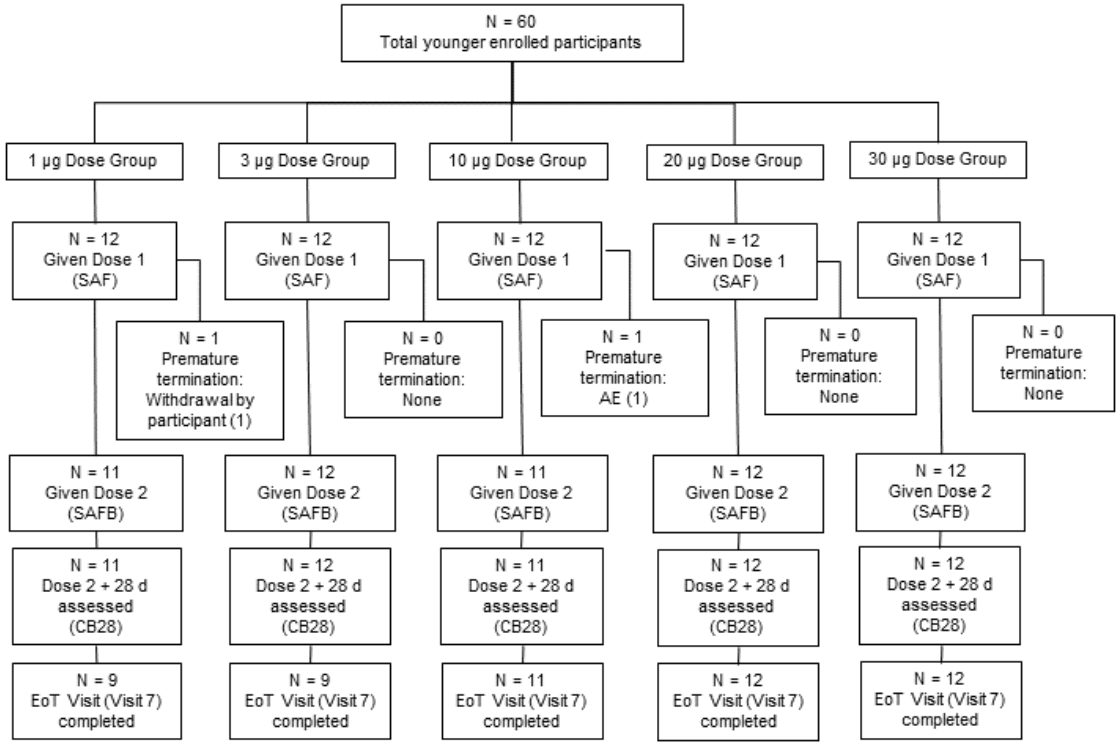

Figure 4: Disposition of younger participants – BNT162b2

AE = adverse event; EoT Visit (Visit 7) completed = end of treatment visit completed (as recorded in the database at the 23 OCT 2020 data cut-off date); N = number of participants; SAF = safety set; SAFB = safety boost set; Dose 2 + 28 d assessed (CB28) = Dose 2 + 28 d completer set.

Source: Based on data from Table 14.1-2-3, Table 14.1-3.1-3, and Listing 16.2.1-1-3.

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The disposition of the 36 older participants is given in Figure 5.

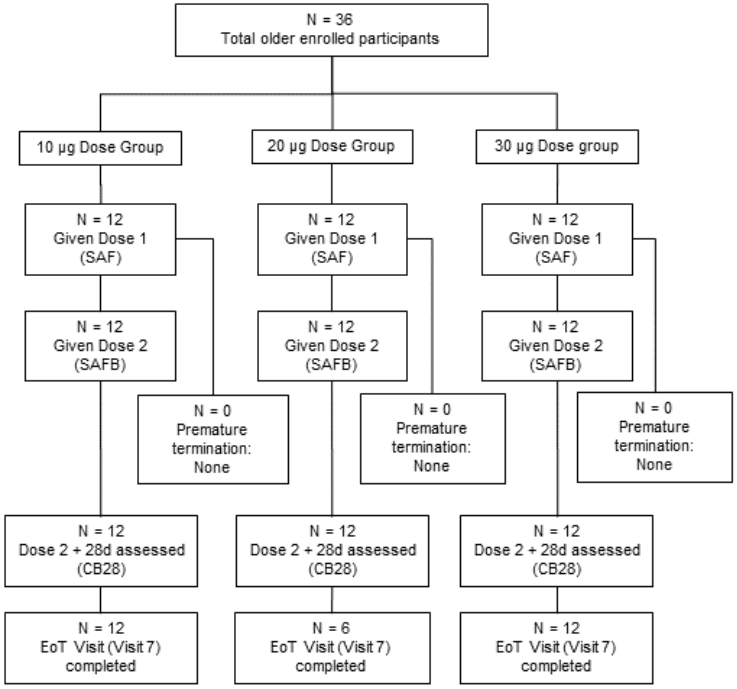

Figure 5: Disposition of older participants – BNT162b2

EoT Visit (Visit 7) completed = end of treatment visit completed (as recorded in the database at the 23 OCT 2020 data cut-off date); N = number of participants; SAF = safety set; SAFB = safety boost set; Dose 2 + 28 d assessed (CB28) = Dose 2 + 28 d completer set.

Source: Based on data from Table 14.1-2-3, Table 14.1-3.1-3, and Listing 16.2.1-1-3.

A total of 60 younger participants and 36 older participants (in total 96 participants) were enrolled in BNT162b2 dose groups in Part A of this study. At the data cut-off (23 OCT 2020), the Dose 2 + 28 d completer set comprised 58 of 60 younger and 36 of 36 older participants (Table 14.1-2-3), and 53 of 60 younger and 30 of 36 older participants had completed Visit 7 (the EoT Visit) (Listing 16.2.1-1-3).

One younger participant (Participant 20116 in the 10 µg dose group) discontinued prematurely due to AEs after Dose 1; these AEs were assessed as not related to the IMP by the investigator; for details see Section 12.6.2.

One younger participant (Participant 20160 in the 1 µg dose group) discontinued prematurely due to "withdrawal by the participant" after Dose 1.

No older participants were prematurely discontinued during the course of the study.

For details, see the Listing 16.2.1-1-3 and Listing 16.2.1-3-3.

10.2 Protocol deviations (investigator-reported)

Protocol deviations are failures to adhere to the inclusion/exclusion criteria and protocol requirements and will be classified into major protocol deviations and minor protocol deviations in the final CSR. In this interim CSR, the protocol deviations reported up to the reactogenicity, safety, disposition, and immunogenicity data cut-off date for this report are listed without classification in the Listing 16.2.1-2-1 and Listing 16.2.1-2-3.

In total, there were 151 (for BNT162b1) and 53 (for BNT162b2) protocol deviations. See Table 3 for a summary of the coded reasons for these protocol deviations. The protocol deviations were reviewed by the sponsor and are considered not to have impacted either GCP compliance, participant safety, or the statistical analyses.

Table 3: Summary of the coded reasons for these protocol deviations

Coded reason	BNT162b1	BNT162b2
Laboratory data, electrocardiogram data, pregnancy data	31	11
Other	30	5
Medical history and concomitant diseases	0	1
Treatment compliance	17	15
Visit schedule compliance	73	21
Total number	151	53

Source: prepared using data provided in Listing 16.2.1-2-1 and Listing 16.2.1-2-3.

10.3 Unblinding of single participants

Not applicable (this is an open-label study).

10.4 Data sets analyzed

10.4.1 Datasets – Reactogenicity and safety

The data cut-off for reactogenicity and safety data is 23 OCT 2020.

BNT162b1

Analyses of participant populations were performed according to the sets defined in Section 9.10.1.2. An overview of the different analysis sets is shown in Table 4 and Table 5.

A by participant listing was prepared which states the reasons for excluding participants from the analysis populations (Listing 16.2.1-4.1-1 and Listing 16.2.1-4.2-1).

Table 4: Analysis sets – BNT162b1 Younger participants (SAF)

	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Safety Set (SAF)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
Safety boost set (SAFB)	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	0 (0)	69 (82)
Dose 1 + 7 d completer set (CP7)	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	83 (99)
Dose 1 to Dose 2 or Dose 1 + 28 d completer set (CPBP28)	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	81 (96)
Dose 2 + 7 d completer set (CB7)	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	0 (0)	69 (82)
Dose 2 + 28 d completer set (CB28)	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	0 (0)	69 (82)
Dose 1 or Dose 2 + 28 d completer set (CPB28)	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	81 (96)

The denominator for the percentage calculation is N.
d = days; N = number of participants in the analysis set; n = number of participants with the specified characteristic.
Source: Table 14.1-2-1.

Table 5: Analysis sets – BNT162b1 Older participants and all participants (SAF)

	Older participants				All
	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Safety Set (SAF)	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
Safety boost set (SAFB)	12 (100)	11 (92)	12 (100)	35 (97)	104 (87)
Dose 1 + 7 d completer set (CP7)	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)
Dose 1 to Dose 2 or Dose 1 + 28 d completer set (CPBP28)	12 (100)	12 (100)	12 (100)	36 (100)	117 (98)
Dose 2 + 7 d completer set (CB7)	12 (100)	11 (92)	12 (100)	35 (97)	104 (87)
Dose 2 + 28 d completer set (CB28)	12 (100)	0 (0)	0 (0)	12 (33)	81 (68)
Dose 1 or Dose 2 + 28 d completer set (CPB28)	12 (100)	1 (8)	0 (0)	13 (36)	94 (78)

The denominator for the percentage calculation is N.
All = all younger and older participants; d = days; N = number of participants in the analysis set; n = number of participants with the specified characteristic.
Source: Table 14.1-2-1.

BNT162b2

Analyses of participant populations were performed according to the sets defined in Section 9.10.1.2. An overview of the different analysis sets is shown in Table 6 and Table 7.

A by participant listing was prepared which states the reasons for excluding participants from the analysis populations (Listing 16.2.1-4.1-3 and Listing 16.2.1-4.2-3).

Table 6: Analysis sets – BNT162b2 Younger participants (SAF)

	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Safety Set (SAF)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
Safety boost set (SAFB)	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
Dose 1 + 7 d completer set (CP7)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
Dose 1 to Dose 2 or Dose 1 + 28 d completer set (CPBP28)	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	59 (98)
Dose 2 + 7 d completer set (CB7)	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
Dose 2 + 28 d completer set (CB28)	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
Dose 1 or Dose 2 + 28 d completer set (CPB28)	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	59 (98)

The denominator for the percentage calculation is N.
d = day(s); N = number of participants in the analysis set; n = number of participants with the specified characteristic.
Source: Table 14.1-2-3.

Table 7: Analysis sets – BNT162b2 Older participants and all participants (SAF)

	Older participants				All
	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Safety Set (SAF)	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
Safety boost set (SAFB)	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
Dose 1 + 7 d completer set (CP7)	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
Dose 1 to Dose 2 or Dose 1 + 28 d completer set (CPBP28)	12 (100)	12 (100)	12 (100)	36 (100)	95 (99)
Dose 2 + 7 d completer set (CB7)	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
Dose 2 + 28 d completer set (CB28)	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
Dose 1 or Dose 2 + 28 d completer set (CPB28)	12 (100)	12 (100)	12 (100)	36 (100)	95 (99)

The denominator for the percentage calculation is N.
All = all younger and older participants; d = days; N = number of participants in the analysis set; n = number of participants with the specified characteristic.
Source: Table 14.1-2-3.

10.4.2 Datasets – Immunogenicity assessments

The data cut-off date for immunogenicity set (IMM) is 23 OCT 2020; this data includes data up to Day 43 for BNT162b1 and data up to Day 85 for BNT162b2.

An overview of the different analysis sets is shown in Table 8.

Table 8: Immunogenicity analysis sets

	Younger participants							
IMP - Age group	1 µg (N=12) n (%)	3 µg (N=0) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
BNT162b1	12 (100)	0 (0)	12 (100)	0 (0)	12 (100)	12 (100)	12 (100)	60 (71)

	Older participants			
	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)
BNT162b1	0 (0)	0 (0)	0 (0)	0 (0)

	Younger participants					
	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
BNT162b2	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)

	Older participants			
	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)
BNT162b2	0 (0)	12 (100)	0 (0)	12 (33)

The denominator for the percentage calculation is N.
d = days; N = number of participants in the analysis set; n = number of participants with the specified characteristic.
Source: Report R-20-0253.

10.4.3 Datasets – CMI assessments

The data cut-off dates are: T-cell response data (ELISpot) data (02 MAR 2021); ICS data (17 NOV 2020 for BNT162b1) and (02 MAR 2021 for BNT162b2).

An overview of the different CMI analysis sets is shown in Table 9.

Table 9: CMI analysis sets

Dose (µg) / age group	Intracellular cytokine staining		SARS-CoV-2 RBD-specific CD4+ and CD8+ T-cell response	
	BNT162b1 (n=95)	BNT162b2 (n=79)	BNT162b1 (n=97)	BNT162b2 (n=76)
1 / younger participants	10	8	11	9
3 / younger participants	10	9	11	10
10 / younger participants	10	11 (2 [a])	11	9
20/ younger participants	6	11 (11 [a])	8	9
30/ younger participants	12	11 (10 [a])	10	10
50/ younger participants	9	NA	10	NA
60/ younger participants	11	NA	9	NA
10 / older participants	8	11 (4 [a])	8	10
20 / older participants	8	9 (7 [a])	8	9
30 / older participants	11	9 (7 [a])	11	10

a) n (number of participants) for which durability data is reported, i.e., data at Days 43, 85, and 184 (i.e., 3, 9, and 23 wks post-Dose 2, respectively).

n = number of participants from which peripheral blood mononuclear cell fractions were available and evaluable; NA = not available; RBD = receptor binding domain.

Source: Interim reports R-20-0235, R-20-0241, R-20-0244.

10.5 Demographic and other baseline characteristics

10.5.1 BNT162b1

BNT162b1 – Younger participants aged 18 to 55 yrs

In total 84 younger participants were treated with BNT162b1 and included in the Safety Set. All participants met the inclusion criteria for age, weight, and BMI (Table 10). Across the dose groups, the mean (SD) participant age was 38.30 (10.99) yrs, the mean (SD) weight was 75.79 (13.52) kg, and the mean (SD) participant BMI was 25.00 (2.87) kg/m^2. Of the younger participants, 44 (52%) were male and 40 (48%) were female, 81 (96%) participants were White, and 82 (98%) participants were not of Hispanic or Latino origin (Table 14.1-4.2-1).

Participant demographics are listed in Listing 16.2.1-5-1.

Table 10: Descriptive statistics for demographic parameters – BNT162b1 younger participants (SAF)

		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Age [years]	N	12	12	12	12	12	12	12	84
	Mean (SD)	38.21 (10.48)	41.44 (11.27)	43.62 (11.03)	39.42 (11.41)	35.74 (8.60)	33.88 (10.72)	35.81 (12.50)	38.30 (10.99)
	Min	21.4	23.8	25.1	20.9	23.9	19.9	20.9	19.9
	Max	55.8	55.2	55.0	55.8	54.0	47.8	53.2	55.8
Weight [kg]	N	12	12	12	12	12	12	12	84
	Mean (SD)	72.99 (14.79)	77.11 (14.07)	71.57 (14.09)	73.58 (11.88)	79.84 (13.81)	76.73 (13.32)	78.70 (13.85)	75.79 (13.52)
	Min	50.1	57.6	54.5	55.1	59.0	57.4	62.2	50.1
	Max	97.0	110.2	100.5	103.7	97.0	97.0	105.6	110.2
BMI [kg/m^2]	N	12	12	12	12	12	12	12	84
	Mean (SD)	25.17 (2.89)	24.94 (2.68)	24.20 (2.32)	24.34 (2.33)	25.68 (3.44)	25.52 (3.50)	25.19 (3.09)	25.00 (2.87)
	Min	21.2	20.9	21.0	20.6	20.2	19.6	19.8	19.6
	Max	29.6	29.3	28.7	28.1	29.8	29.9	29.8	29.9

BMI = body mass index; N = number of participants in the analysis set; min = minimum; max = maximum; n = number of participants with data available; SAF = Safety Set; SD = standard deviation.
Source: modified from Table 14.1-4.1-1.

BNT162b1 – Older participants aged 56 to 85 yrs

In total, 36 older participants were treated with BNT162b1 and included in the Safety Set. All older participants met the inclusion criteria for age, weight, and BMI (Table 11). Across the dose groups, the mean participant ages, weights, and BMIs values were comparable.

Of the older participants, 13 (36%) were male and 23 (64%) were female. All 36 older participants were White and none were of Hispanic or Latino origin (Table 14.1-4.2-1). The mix of male and female participants per dose group varied, but with one exception always included more females than males. In the 20 µg dose, 10 of 12 participants were female. This difference was not considered relevant for the study objectives.

Table 11: Descriptive statistics for demographic parameters – BNT162b1 older participants and all participants (SAF)

		Older participants				All
		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Age [years]	N	12	12	12	36	120
	Mean (SD)	64.31 (5.89)	65.66 (5.95)	67.16 (6.47)	65.71 (6.05)	46.53 (15.94)
	Min	56.1	57.0	57.3	56.1	19.9
	Max	73.9	75.8	76.8	76.8	76.8
Weight [kg]	N	12	12	12	36	120
	Mean (SD)	71.90 (10.98)	70.38 (9.14)	69.98 (8.06)	70.75 (9.23)	74.28 (12.57)
	Min	55.6	57.6	60.3	55.6	50.1
	Max	91.7	87.2	87.1	91.7	110.2
BMI [kg/m^2]	N	12	12	12	36	120
	Mean (SD)	24.73 (2.46)	25.59 (2.22)	25.63 (2.22)	25.32 (2.28)	25.10 (2.70)
	Min	20.7	22.8	22.5	20.7	19.6
	Max	27.4	28.5	28.6	28.6	29.9

All = all younger and older participants; BMI = body mass index; N = number of participants in the analysis set; min = minimum; max = maximum; n = number of participants with data available; SAF = Safety Set; SD = standard deviation.
Source: modified from Table 14.1-4.1-1.

In total 120 younger and older participants were treated with BNT162b1 and included in the Safety Set. All participants met the inclusion criteria for age, weight, and BMI (Table 11). Across the dose groups, the mean (standard deviation, SD) participant age was 46.53 (15.94) yrs, the mean (SD) weight was 74.28 (12.57) kg, the mean (SD) participant BMI was 25.10 (2.70) kg/m^2. Of the participants, 57 (48%) were male and 63 (53%) were female, 117 (98%) participants were White (there were 2 Asian and 1 Black participants), and 118 (98%) participants were not of Hispanic or Latino origin (Table 14.1-4.2-1).

Participant demographics are listed in Listing 16.2.1-5-1.

10.5.2 BNT162b2

BNT162b2 – Younger participants aged 18 to 55 yrs

In total 60 younger participants were treated with BNT162b2 and included in the Safety Set. All participants met the inclusion criteria for age, weight, and BMI (Table 12).

Across the dose groups, the mean (standard deviation, SD) participant age was 40.26 (10.20) yrs, the mean (SD) weight was 76.72 (11.26) kg, the mean (SD) participant BMI was 25.27 (2.37) kg/m^2. Across the dose groups, the mean participant weights and BMIs were comparable, the mean participant ages in the 20 µg and 30 µg were increasingly older (i.e., 42.75 and 47.21 yrs) than in 1 µg, 3 g, and 10 µg dose groups (i.e., 36.65, 39.64, and 35.07 yrs). This difference was not considered relevant for the study objectives.

Of the participants, 26 were male and 34 were female. All participants were White and there were no participants of Hispanic or Latino origin (Table 14.1-4.2-3).

Participant demographics are listed in Listing 16.2.1-5-3.

Table 12: Descriptive statistics for demographic parameters – BNT162b2 younger participants (SAF)

		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Age [years]	N	12	12	12	12	12	60
	Mean (SD)	36.65 (10.14)	39.64 (10.14)	35.07 (10.46)	42.75 (9.89)	47.21 (6.43)	40.26 (10.20)
	Min	21.6	24.6	19.0	29.4	35.8	19.0
	Max	53.4	55.8	51.5	55.8	55.7	55.8
Weight [kg]	N	12	12	12	12	12	60
	Mean (SD)	80.18 (14.13)	77.08 (10.84)	76.11 (11.67)	72.45 (10.97)	77.78 (8.43)	76.72 (11.26)
	Min	55.7	57.2	60.6	56.9	60.6	55.7
	Max	99.1	98.0	97.1	90.2	86.0	99.1
BMI [kg/m²]	N	12	12	12	12	12	60
	Mean (SD)	25.25 (3.26)	25.50 (2.79)	25.13 (2.07)	25.43 (2.34)	25.01 (1.38)	25.27 (2.37)
	Min	19.5	22.0	22.0	21.2	22.8	19.5
	Max	29.8	29.8	29.0	29.0	27.4	29.8

BMI = body mass index; N = number of participants in the analysis set; min = minimum; max = maximum; n = number of participants with data available; SAF = Safety Set; SD = standard deviation.
Source: modified from Table 14.1-4.1-3.

BNT162b2 – Older participants aged 56 to 85 yrs

In total 36 older participants were treated with BNT162b2 and included in the Safety Set. All participants met the inclusion criteria for age, weight, and BMI (Table 13). Across the dose groups, the mean participant ages, weights, and BMIs were comparable. Of the older participants, 18 were male and 18 were female. All participants were White and there were no participants of Hispanic or Latino origin (Table 14.1-4.2-3).

Table 13: Descriptive statistics for demographic parameters – BNT162b2 older participants and all participants (SAF)

		Older participants				All
		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Age [years]	N	12	12	12	36	96
	Mean (SD)	65.44 (7.42)	65.88 (6.56)	63.87 (5.42)	65.06 (6.39)	49.56 (15.01)
	Min	56.9	56.8	57.0	56.8	19.0
	Max	84.0	80.6	73.4	84.0	84.0
Weight [kg]	N	12	12	12	36	96
	Mean (SD)	77.87 (9.78)	76.91 (12.38)	75.80 (11.98)	76.86 (11.14)	76.77 (11.15)
	Min	55.5	57.7	60.4	55.5	55.5
	Max	91.0	101.8	94.6	101.8	101.8
BMI [kg/m^2]	N	12	12	12	36	96
	Mean (SD)	25.43 (2.15)	25.62 (2.47)	25.85 (2.75)	25.63 (2.40)	25.40 (2.38)
	Min	21.8	22.6	21.9	21.8	19.5
	Max	28.4	29.7	29.4	29.7	29.8

All = all younger and older participants; BMI = body mass index; N = number of participants in the analysis set; min = minimum; max = maximum; n = number of participants with data available; SAF = Safety Set; SD = standard deviation.
Source: modified from Table 14.1-4.1-3.

In total 96 younger and older participants were treated with BNT162b2 and included in the Safety Set. All participants met the inclusion criteria for age, weight, and BMI (Table 13). Across the dose groups, the mean (SD) participant age was 49.56 (15.01) yrs, the mean (SD) weight was 76.77 (11.15) kg, the mean (SD) BMI was 25.40 (2.38) kg/m^2. In total, 44 (46%) were male and 52 (54%) were female, 96 (100%) participants were White, and 96 (100%) participants were not of Hispanic or Latino origin (Table 14.1-4.2-3).

Participant demographics are listed in Listing 16.2.1-5-3.

10.6 Prior and concomitant medication

For a listing of prior medication, see Listing 16.2.1-6.1-1 (BNT162b1) and Listing 16.2.1-6.1-3 (BNT162b2). All participants met the exclusion criteria with respect to prior medications.

For a listing of concomitant medication, see Listing 16.2.1-6.2-1 (BNT162b1) and Listing 16.2.1-6.2-3 (BNT162b2).

There were no concomitant medications which, in the opinion of the investigator and sponsor, would have compromised participant wellbeing, or that could prevent, limit, or confound the protocol-specified assessments.

10.7 Medical history

For a listing of medical history, see Listing 16.2.1-7-1 (BNT162b1) and Listing 16.2.1-7-3 (BNT162b2). All participants met the inclusion criteria with respect to medical history.

10.8 Measurement of treatment compliance

The IMPs were administered under supervision of the investigator and the IMP compliance was recorded in the CRFs is summarized in Table 14 (BNT162b1) and Table 15 (BNT162b2).

Table 14: IMP compliance – BNT162b1 (SAF)

	Younger participants							
	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Subjects receiving Dose 1	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
Subjects receiving Dose 2	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	0 (0)	69 (82)

	Older participants				All
	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Subjects receiving Dose 1	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
Subjects receiving Dose 2	12 (100)	11 (92)	12 (100)	35 (97)	104 (87)

All participants = all younger and older participants; N = number of participants in the analysis set; n = number of participants with data available; SAF = Safety Set.
Source: Table 14.3.2-1.1-1.

Table 15: IMP compliance – BNT162b2 (SAF)

	Younger participants					
	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Subjects receiving Dose 1	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
Subjects receiving Dose 2	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)

	Older participants				All
	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Subjects receiving Dose 1	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
Subjects receiving Dose 2	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)

All = all younger and older participants; N = number of participants in the analysis set; n = number of participants with data available; SAF = Safety Set.
Source: Table 14.3.2-1.1-3.

The exact IMP administration times were recorded in the CRF and are listed in the Listing 16.2.3-2.1-1 (BNT162b1) and Listing 16.2.3-2.1-3 (BNT162b2).

11 IMMUNOGENICITY, CELL-MEDIATED IMMUNE RESPONSE, AND GENETICS RESULTS

11.1 Immunogenicity – functional antibody responses (secondary objective)

For an overview of the IMM analysis set, see Section 10.4.

Data for functional neutralizing antibody titers are available up until Day 43 for BNT162b1-dosed younger participants aged 18 to 55 yrs dosed with 1, 10, 30, 50, and 60 µg on Days 1 (all dose levels) and 22 (all dose levels except 60 µg) (n=12 per group). For BNT162b2-dosed participants, functional neutralizing antibody titers are available for younger participants aged 18 to 55 yrs dosed with 1, 3, 10, 20, and 30 µg, and older participants aged 56 to 85 yrs dosed with 20 µg on Days 1 and 22 (n=12 per group).

For BNT162b2-dosed participants, functional antibody data for younger participants is available up until Day 50 for dose groups 1 µg and 3 µg, and up until Day 85 for dose groups 10, 20, and 30 µg. For the older participants, data is available up until Day 29 (Section 9.11).

For virus neutralizing antibody GMTs (neutralizing GMTs) and 95% confidence intervals for participants aged 18 to 55 yrs after dosing with BNT162b1, see Figure 6 (50% neutralizing titer).

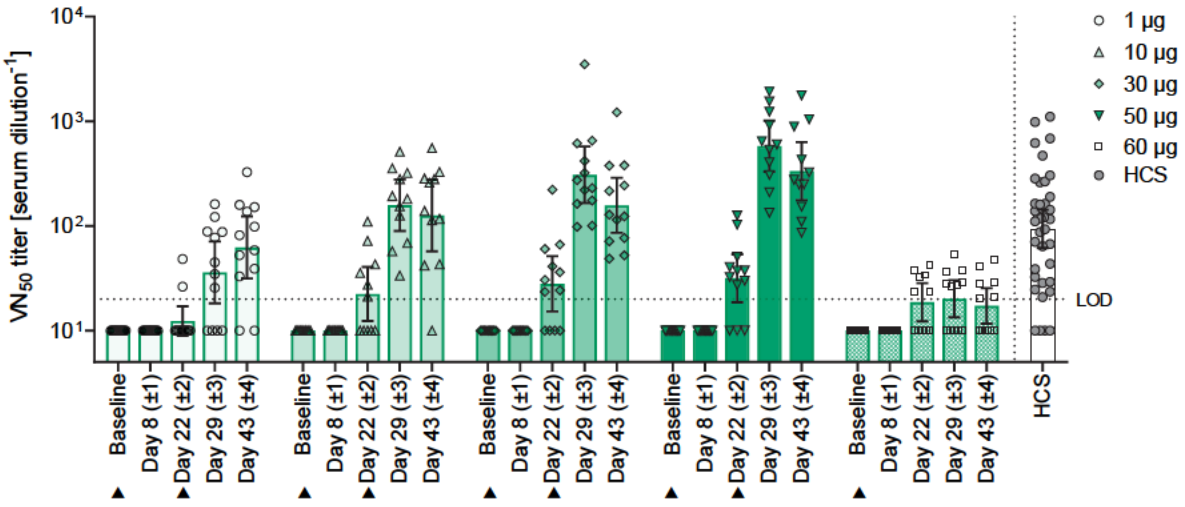

Figure 6: BNT162b1 – Functional 50% SARS-CoV-2 neutralizing antibody titers (VN_{50}) – IMM

VN_{50} titers with 95% confidence intervals are shown for younger participants (aged 18 to 55 years) immunized with 1, 10, 30, 50, or 60 µg BNT162b1. Values smaller than the limit of detection (LOD) are plotted as 0.5*LOD. Arrowheads indicate baseline (pre-Dose 1, Day 1) and Dose 2 (Day 22). Dose 2 was not performed in the 60 µg dose group. The dotted horizontal line represents the LOD.

IMM = Immunogenicity set; VN_{50} = 50% SARS-CoV-2 neutralizing ant body titers; HCS = human COVID-19 convalescent serum.

Source: Report R-20-0253.

For neutralizing GMTs and 95% confidence intervals for younger participants aged 18 to 55 yrs and older participants aged 56 to 85 yrs after dosing with BNT162b2, see Figure 7 (50% neutralizing titer).

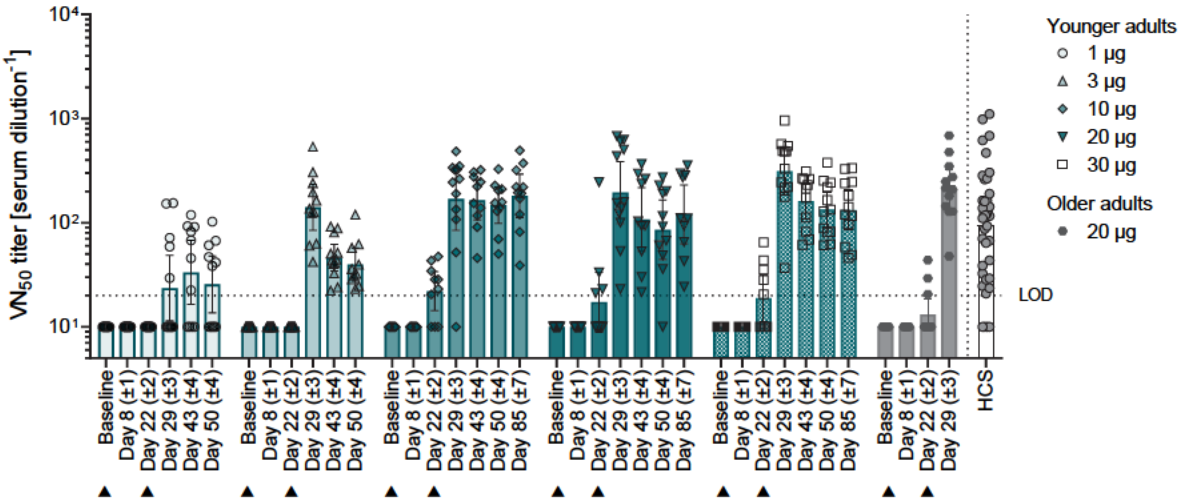

Figure 7: BNT162b2 – Functional 50% SARS-CoV-2 neutralizing antibody titers (VN_{50}) – IMM

VN_{50} titers with 95% confidence intervals are shown for younger adults (aged 18 to 55 years) immunized with 1, 3, 10, 20, or 30 µg BNT162b2, and older adults (aged 56 to 85 yrs) immunized with 20 µg BNT162b2. Values smaller than the limit of detection (LOD) are plotted as 0.5*LOD. Arrowheads indicate baseline (pre-Dose 1, Day 1) and Dose 2 (Day 22). The dotted horizontal line represents the LOD.

IMM = Immunogenicity set; VN_{50} = 50% SARS-CoV-2 neutralizing ant body titers; HCS = human COVID-19 convalescent serum.

Source: Report R-20-0253.

Fold increase from baseline in functional antibody titer data is displayed in Figure 8 (BNT162b1) and Figure 9 (BNT162b2).

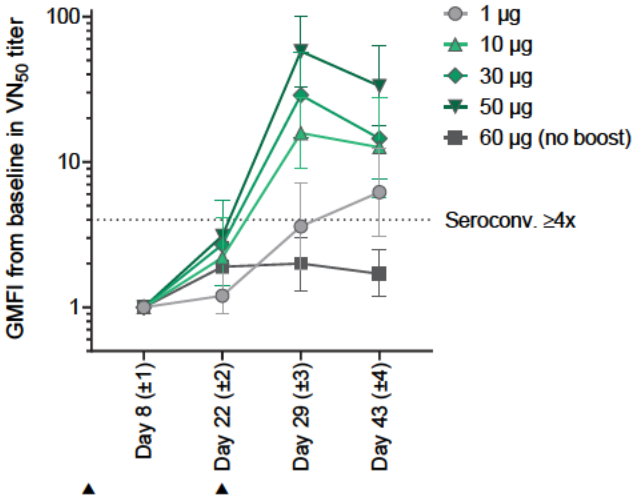

Figure 8: BNT162b1 – Fold increase from baseline in functional 50% SARS-CoV-2 neutralizing antibody titers (VN_{50}) – IMM

Geometric means fold increase (GMFI) from baseline in VN_{50} titer with 95% confidence intervals are shown for younger participants (aged 18 to 55 yrs) immunized with 1, 10, 30, 50, or 60 µg BNT162b1. Arrowheads indicate baseline (pre-Dose 1, Day 1) and Dose 2 (Day 22). Dose 2 was not performed in the 60 µg dose group. The dotted horizontal line represents the threshold for seroconversion (fold increase ≥4).

IMM = Immunogenicity set; VN_{50} = 50% SARS-CoV-2 neutralizing ant body titers.

Source: Report R-20-0253.

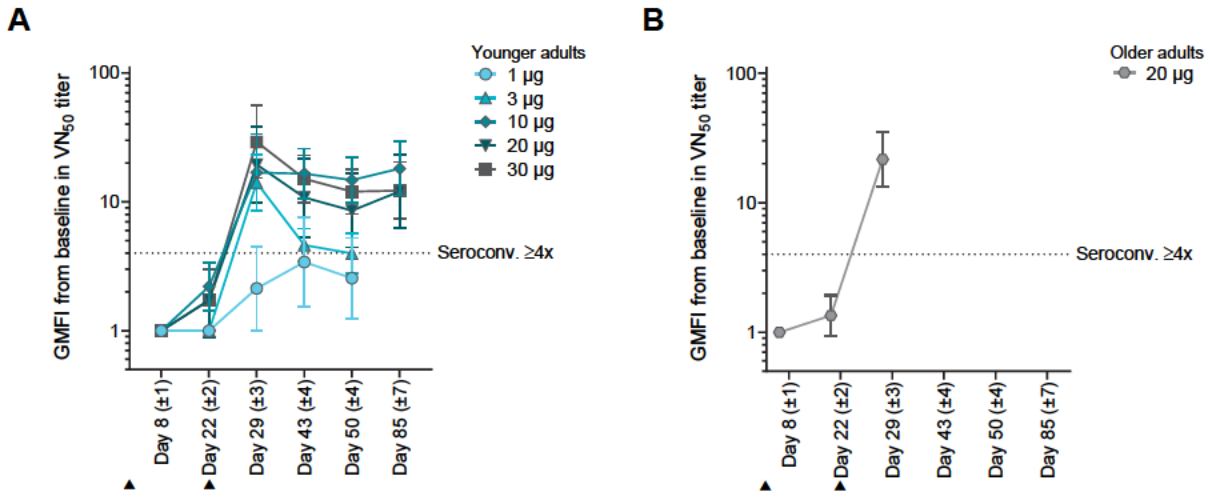

Figure 9: BNT162b2 – Fold increase from baseline in functional 50% SARS-CoV-2 neutralizing antibody titers (VN_{50}) – IMM

Geometric means fold increase (GMFI) from baseline in VN_{50} titer with 95% confidence intervals are shown for (**A**) younger participants (aged 18 to 55 yrs) immunized with 1, 3, 10, 20, or 30 µg BNT162b2, and (**B**) older participants (aged 56 to 85 yrs) immunized with 20 µg BNT162b2. Arrowheads indicate baseline (pre-Dose 1, Day 1) and Dose 2 (Day 22). The dotted horizontal line represents the threshold for seroconversion (fold increase ≥4).

IMM = Immunogenicity set; VN_{50} = 50% SARS-CoV-2 neutralizing ant body titers.

Source: Report R-20-0253.

Participants dosed with BNT162b1 showed a strong dose-dependent antibody response. On Day 22, at 21 d after Dose 1, virus neutralizing antibody GMTs (neutralizing GMTs) had increased in a dose-dependent manner for the 1, 10, 30, and 50 µg dose groups. At 7 d after Dose 2 (Day 29), neutralizing GMTs showed a strong, dose level dependent booster response. In the 60 µg dose group, which was only dosed once, neutralizing GMTs remained at a lower level, indicating that a booster dose is necessary to increase functional antibody titers.

On Day 43 (21 d after the Dose 2 of BNT162b1), neutralizing GMTs decreased (with exception of the 1 µg dose level). Day 43 virus neutralizing GMTs were 0.7-fold (1 µg) to 3.6-fold (50 µg) those of a COVID-19 HCS panel.

The COVID-19 HCS panel is comprised of 38 human COVID-19 HCS sera drawn from individuals aged 18 to 85 yrs, at least 14 d after confirmed diagnosis, and at a time when the individuals were asymptomatic. The serum donors predominantly had symptomatic infections (35/38), and one had been hospitalized. The sera were obtained from Sanguine Biosciences (Sherman Oaks, CA), the MT Group (Van Nuys, CA), and Pfizer Occupational Health and Wellness (Pearl River, NY).

Participants dosed with BNT162b2 showed a strong IMP-induced antibody response. Virus neutralizing GMTs were detected at 21 d after Dose 1 (Day 22) and had increased substantially in younger participants (aged 18 to 55 yrs) immunized with ≥3 µg BNT162b2, and older participants (aged 56 to 85 yrs) immunized with 20 µg BNT162b2 by 7 d after Dose 2 (Day 29). Day 29 virus neutralizing GMTs were comparable between the younger and older adult 20 µg dose groups. The lowest tested dose of 1 µg BNT162b2 elicited only a minimal neutralizing response in participants aged 18 to 55 yrs.

On Day 43 (21 d after Dose 2 of BNT162b2), virus neutralizing GMTs in the younger adult dose groups decreased for the 3, 20, and 30 µg dose levels. Thereafter, neutralizing GMTs in between Days 29 and 43, neutralizing GMTs remained stable up to Day 85 (63 d after Dose 2) for younger adult dose groups 10, 20, and 30 µg and were 1.3-fold to 1.9-fold those of a COVID-19 HCS panel.

Seroconversion is defined as a minimum of a 4-fold increase of antibody GMT as compared to baseline. The frequency of participants with seroconversion is displayed in Figure 10 (BNT162b1) and Figure 11 (BNT162b2).

All participants dosed with Dose 1 at ≥30 µg BNT162b1 or BNT162b2 seroconverted either by 7 d or 21 d after Dose 2 (Day 29 or Day 43). All participants dosed with 30 µg BNT162b2 remained seropositive throughout the follow-up until Day 85.

For further details on the functional antibody responses against the SARS-CoV-2 S protein S1 subunit, see the interim report R-20-0253.

The methodology used for the assessments and complete results are presented in the interim report R-20-0253.

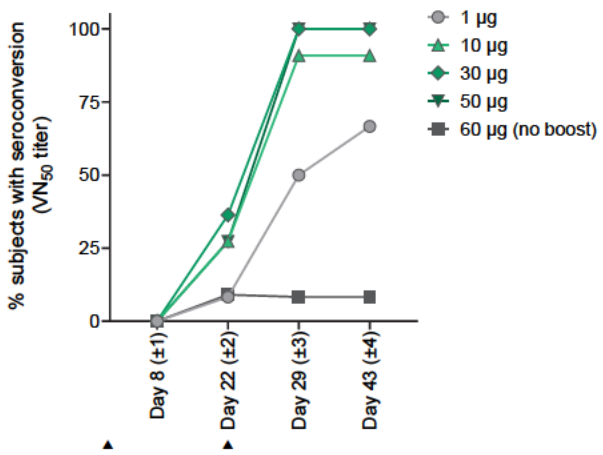

Figure 10: BNT162b1 – Frequency of participants with SARS-CoV-2 GMT seroconversion – IMM

Seroconversion with regard to 50% SARS-CoV-2 neutralizing ant body titers (VN_{50}) is shown for younger participants (aged 18 to 55 yrs) immunized with 1, 10, 30, 50, or 60 µg BNT162b1. Seroconversion is defined as a minimum of a 4-fold increase of functional ant body response as compared to baseline. Arrowheads indicate baseline (pre-Dose 1, Day 1) and Dose 2 (Day 22). Dose 2 was not performed in the 60 µg dose group.

GMT = geometric mean titer; IMM = Immunogenicity set.

Source: Report R-20-0253.

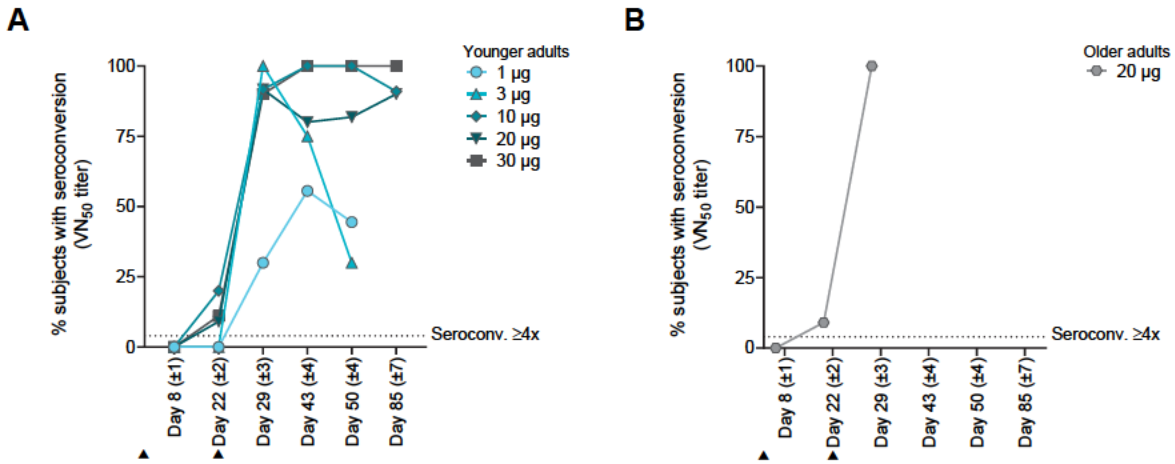

Figure 11: BNT162b2 – Frequency of participants with SARS-CoV-2 GMT seroconversion – IMM

Seroconversion with regard to 50% SARS-CoV-2 neutralizing ant body titers (VN_{50}) is shown for (**A**) younger participants (aged 18 to 55 yrs) dosed with 1, 3, 10, 20, or 30 µg BNT162b2, and (**B**) older participants (aged 56 to 85 yrs) dosed with 20 µg BNT162b2. Seroconversion is defined as a minimum of 4-fold increase of functional antibody response as compared to baseline. Arrowheads indicate baseline (pre-Dose 1, Day 1) and Dose 2 (Day 22).

GMT = geometric mean titer; IMM = Immunogenicity set.

Source: Report R-20-0253.

11.2 Immunogenicity – binding antibody concentrations (exploratory objective)

For an overview of the IMM analysis set, see Section 10.4.

Binding antibody concentration data is available up until Day 43 for BNT162b1-dosed younger participants aged 18 to 55 yrs dosed with 1, 10, 30, 50, or 60 µg on Days 1 (all dose levels) and 22 (all dose levels except 60 µg) (n=12 per group).

For BNT162b2-dosed participants, data is available for younger participants aged 18 to 55 yrs dosed with 1, 3, 10, 20, or 30 µg, and older participants aged 56 to 85 yrs dosed with 20 µg on Days 1 and 22 (n=12 per group). Binding antibody concentration data for younger participant dose groups is available up until Day 50 for dose groups 1 µg and 3 µg, and up until Day 85 for dose groups 10, 20, and 30 µg. For the BNT162b2-dosed older participants, data is available up until Day 29 (Section 9.11).

The fold increase from baseline in binding antibody concentrations after dosing with BNT162b1 and BNT162b2 is summarized in Figure 12 and Figure 13.

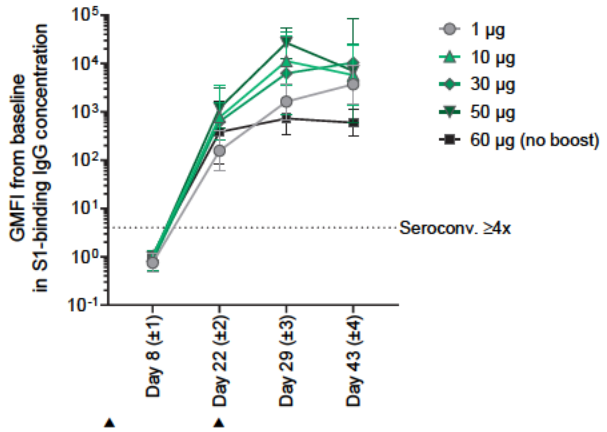

Figure 12: BNT162b1 – Fold increase from baseline in S1-binding antibody concentrations – IMM

Geometric means fold increase (GMFI) from baseline in S1-binding ant body concentrations with 95% confidence intervals are shown for younger participants (aged 18 to 55 yrs) immunized with 1, 10, 30, 50, or 60 µg BNT162b1. Arrowheads indicate baseline (pre-Dose 1, Day 1) and Dose 2 (Day 22). Dose 2 was not performed in the 60 µg dose group. The dotted horizontal line represents the threshold for seroconversion (fold increase ≥4).

IMM = Immunogenicity set.

Source: Report R-20-0253.

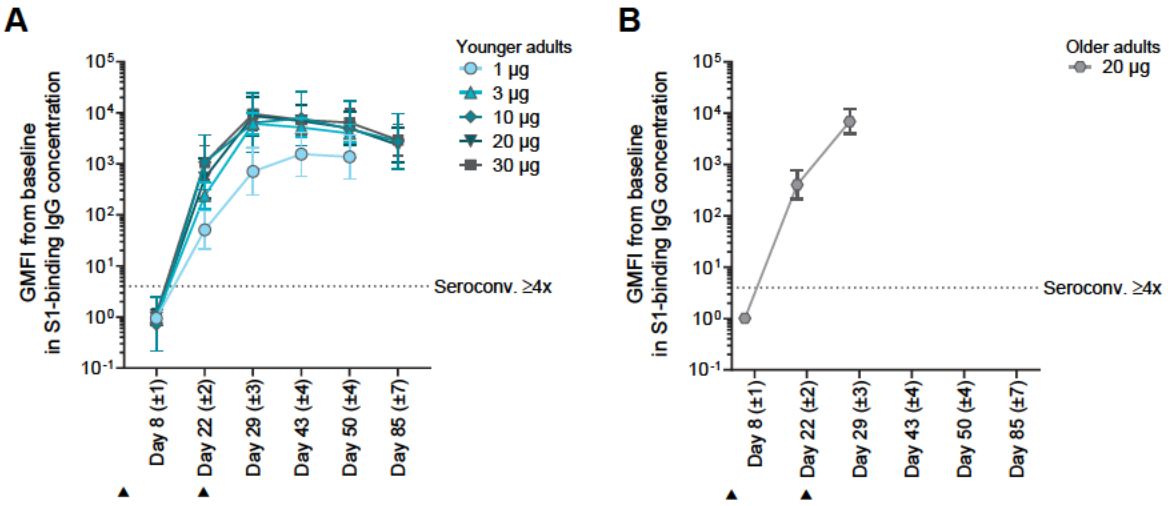

Figure 13: BNT162b2 – Fold increase from baseline in S1-binding antibody concentrations – IMM

Geometric means fold increase (GMFI) from baseline in S1-binding ant body concentrations with 95% confidence intervals are shown for (**A**) younger participants (aged 18 to 55 yrs) immunized with 1, 3, 10, 20, or 30 µg BNT162b2, and (**B**) older participants (aged 56 to 85 yrs) immunized with 20 µg BNT162b2. Arrowheads indicate baseline (pre-Dose 1, Day 1) and Dose 2 (Day 22). The dotted horizontal line represents the threshold for seroconversion (fold increase ≥4).

IMM = Immunogenicity set.

Source: Report R-20-0253.

Participants dosed with BNT162b1 showed a strong dose-dependent antibody response against the SARS-CoV-2 spike (S) protein S1 subunit at 21 d after Dose 1 (Day 22). At 7 d after Dose 2 (Day 29), S1-binding immunoglobulin G (IgG) GMCs showed a strong, dose-dependent booster response. In the 60 µg dose group, which was only dosed once, S1-binding IgG GMCs remained at a lower level, indicating that a booster dose is necessary to increase antibody concentrations.

At 21 d after the Dose 2 of BNT162b1 (Day 43), S1-binding IgG GMCs decreased (with exception of the 1 µg dose group), but were clearly above those of a COVID-19 HCS panel for all doses tested.

BNT162b2 dosed participants showed a strong BNT162b2-induced S1-binding IgG response at 21 d after Dose 1 (Day 22) with evidence of a dose-dependent response only between the 1 µg and 10 µg dose levels. S1-binding IgG GMCs showed a substantial booster response by 7 d after Dose 2 (Day 29). Day 29 S1-binding IgG GMCs were comparable between the younger and older participants at the 20 µg dose level.

Across all dose groups, antibody levels decreased over time, but with S1-binding antibody GMCs well above that observed in a COVID-19 HCS panel at Day 85 (63 d after Dose 2; 10 to 30 µg dose level).

The frequency of participants with seroconversion after dosing with BNT162b1 and BNT162b2 is summarized in Figure 14 and Figure 15.

Almost all BNT162b1- and BNT162b2-immunized participants seroconverted with regard to the S1-binding antibody response as early as 21 d after Dose 1 (Day 22).

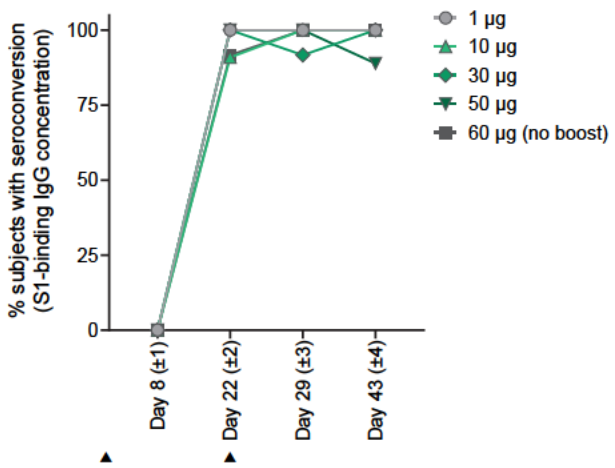

Figure 14: BNT162b1 – Frequency of participants with S1-binding IgG GMC seroconversion – IMM

Seroconversion with regard to S1-binding antibody GMC is shown for younger participants (aged 18 to 55 yrs) immunized with 1, 10, 30, 50, or 60 µg BNT162b1. Seroconversion is defined as at least a 4-fold increase of S1-binding IgG GMC response as compared to baseline. Arrowheads indicate baseline (pre-Dose 1, Day 1) and Dose 2 (Day 22). Dose 2 was not performed in the 60 µg dose group.

GMC = geometric mean concentration; IMM = Immunogenicity set.

Source: Report R-20-0253.

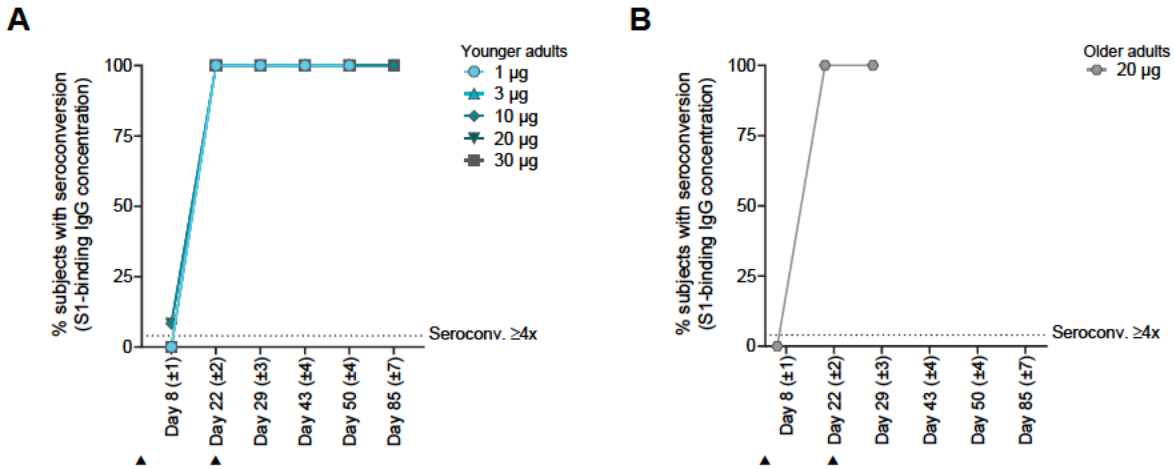

Figure 15: BNT162b2 – Frequency of participants with S1-binding IgG GMC seroconversion – IMM

Seroconversion with regard to S1-binding antibody GMC is shown for (**A**) younger participants (aged 18 to 55 yrs) immunized with 1, 3, 10, 20, or 30 µg BNT162b2, and (**B**) older participants (aged 56 to 85 yrs) dosed with 20 µg BNT162b2. Seroconversion is defined as at least a 4-fold increase of S1-binding IgG GMC response as compared to baseline. Arrowheads indicate baseline (pre-Dose 1, Day 1) and Dose 2 (Day 22).

GMC = geometric mean concentration; IMM = Immunogenicity set.

Source: Report R-20-0253.

Similar observations were made using only the RBD domain as the target antigen. For further details on the methodology used for the assessments, the binding antibody responses against the SARS-CoV-2 S protein S1 subunit and when using only the RBD domain as the target antigen, see the interim report R-20-0253.

11.3 Cell-mediated immune responses

For an overview of the CMI analysis sets, see Section 10.4.

11.3.1 SARS-CoV-2-specific CD4+ and CD8+ T-cell responses

In order to assess immunogenicity of the vaccine candidates, peripheral blood T cells of the study participants were analyzed for $CD4^+$ and $CD8^+$ T cells specific for the SARS-CoV-2 spike protein. This analysis was performed using *ex vivo* interferon γ (IFNγ) ELISpot on blood samples collected on pre-Dose 1 and on Day 29 (i.e., 7 d post-Dose 2). In a subset of study participants who received 10, 20, and 30 µg BNT162b2, blood samples were also collected on Day 85 (i.e., 63 d post-Dose 2) and Day 184 (i.e., 162 d post-Dose 2) and analyzed. The ELISpot assay was performed under GCP conditions within the analytical study GA-RB-022-01A by the Biolytics-GCP test facility, providing an expert call on the presence or absence of T-cell responses, as well as spot count data for each vaccine target in each sample. The spot count data were further processed and normalized based on T-cell fitness/content of each sample, in order to enable accurate interpretation of the immunogenicity of BNT162b1 and BNT162b2.

As of 02 MAR 2021, evaluable $CD4^+$ and $CD8^+$ T-cell response data were available from 97 study participants that received BNT162b1, 70 younger participants at dose levels of 1, 3, 10, 20, 30, 50, or 60 µg (note: Dose 2 was not given in the 60 µg dose group), and 27 older participants at dose levels of 10, 20, or 30 µg. This included:

- Younger participants aged 18 to 55 yrs per dose group: 1 µg (n=11), 3 µg (n=11), 10 µg (n=11), 20 µg (n=8), 30 µg (n=10), 50 µg (n=10), and 60 µg (n=9).
- Older participants 56 to 85 yrs per dose group: 10 µg (n=8), 20 µg (n=8), and 30 µg (n=11).

As of 02 MAR 2021, evaluable $CD4^+$ and $CD8^+$ T-cell response data were available from 76 participants that received BNT162b2 in Dose Groups 1 to 10 at dose levels of 1, 3, 10, 20, or 30 µg (47 younger participants), or 10, 20, or 30 µg (29 older participants). This included:

- Younger participants aged 18 to 55 yrs per dose group: 1 µg (n=9), 3 µg (n=10), 10 µg (n=9), 20 µg (n=9), and 30 µg (n=10).
- Older participants 56 to 85 yrs per dose group: 10 µg (n=10), 20 µg (n=9), and 30 µg (n=10).

To assess the persistence of cell-mediated immune responses, as of 02 MAR 2021, evaluable $CD4^+$/$CD8^+$ T-cell response data at Days 85 and 184 (i.e., 9 and 23 wks post-Dose 2, respectively) are also available for 24 study participants that received BNT162b2 (20 younger participants at dose levels of 10, 20, or 30 µg, and 4 older participants at dose levels of 10, 20, or 30 µg).

The following results are based on assessment of T cell data collected on Day 1 (before Dose 1), Day 29, Day 85, and Day 184 (i.e., 1, 9, and 23 wks post-Dose 2, respectively).

BNT162b1 induced strong RBD-specific $CD4^+$ T-cell responses in the majority of study participants given both Dose 1 and Dose 2 (86 of 88 [97.7%]), including all older

participants (27 of 27 [100%]); $CD8^+$ responses were induced in 47 of 61 (77.0%) younger participants and in 21 of 27 (77.7%) older participants. In contrast, T-cell responses were detected less often and were lower in magnitude in 9 younger participants who received only Dose 1 in the 60 µg dose group, indicating the importance of a booster dose.

BNT162b2 induced strong SARS-CoV-2 S protein-specific $CD4^+$ T-cell responses in all of the dosed younger or older participants (76 of 76 [100%]); $CD8^+$ T-cell responses were induced in 45 of 47 (95.7%) younger participants and 24 of 29 (82.8%) older participants. Despite the slightly lower $CD8^+$ immunogenicity rate in older participants, the magnitude of the BNT162b2-induced responses was comparable to those induced in younger participants who received 30 µg of BNT162b2. These T-cell responses were directed against different parts of the antigen including non-RBD sequences, indicating the induction of multi-epitopic responses by BNT162b2 in both age groups.

Dosing twice with BNT162b1 or BNT162b2 led to a substantial increase in incidence and magnitude of T-cell responses in both age groups, and across all dose levels for BNT162b1. While the magnitude of $CD4^+$ T-cell responses induced by BNT162b2 was also similar across different dose levels, the magnitude of $CD8^+$ T-cell responses was highest at the 30 µg dose level. The participants with the strongest $CD4^+$ T-cell responses had more than 10-fold of the memory responses observed in the same participants against immunodominant peptides from cytomegalovirus, Epstein-Barr virus, influenza virus, and tetanus toxoid. The same participants also had strong $CD8^+$ T-cell responses that were comparable to memory responses against the above mentioned viral antigens.

BNT162b2-induced $CD4^+$ and $CD8^+$ T-cell responses showed a decrease on Day 85, but remained detectable on Day 184 in almost all participants vaccinated with >10 µg at levels higher than or in range of recall antigen memory responses. The durability of BNT162b2-induced T-cell responses is shown in Figure 16.

RBD- and S protein-specific $CD4^+$ T-cell responses observed after vaccination were induced by BNT162b1 in 97.5% of participants and by BNT162b2 in 100% of participants. RBD- and S protein-specific $CD8^+$ T-cell responses observed after vaccination were induced by BNT162b1 in 95.5% of participants and by BNT162b2 in 96.6% of participants.

The methodology used to assess the BNT162b1 and BNT162b2 elicited T-cell responses and complete results are presented in the interim reports GA-RB-022-01A and R-20-0244.

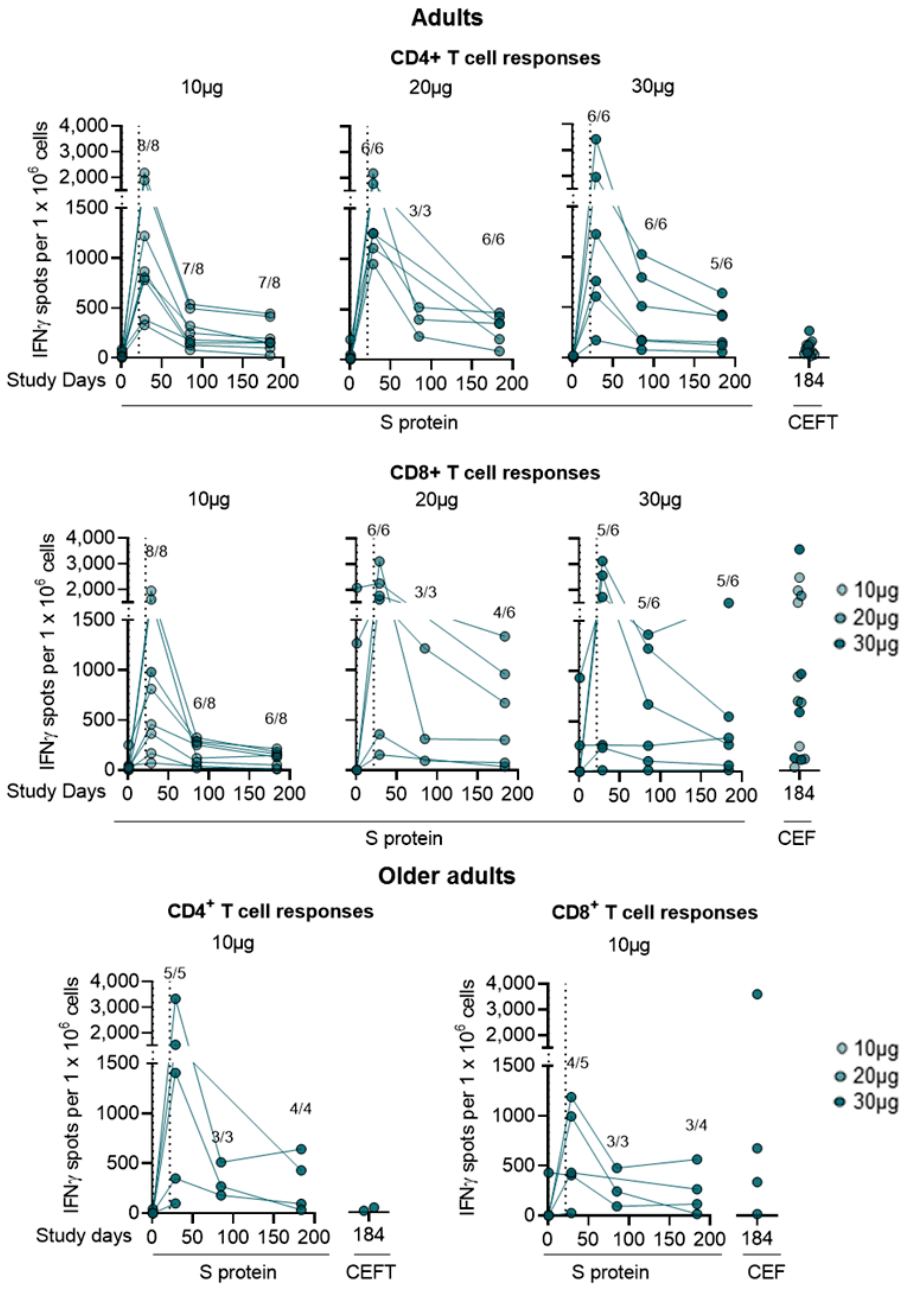

Figure 16: Durability of BNT162b2-induced T-cell responses

PBMCs obtained on Day 1 (before Dose 1), Day 29, Day 85, and Day 184 (7 d, 9 wks, and 23 wks post-Dose 2, respectively), were analyzed in *ex vivo* IFNγ ELISpot (for details see GA-RB-022-01A). Common pathogen T-cell epitope pools CEF (CMV, EBV, and influenza virus HLA class I epitopes) and CEFT (CMV, EBV, influenza virus, and tetanus toxoid HLA class II epitopes) served to assess general T-cell reactivity, cell culture medium served as negative control. Each dot represents the sum of normalized mean spot count from duplicate wells stimulated with two peptide pools corresponding to the full-length wild-type S protein for one study participant, after subtraction of the medium-only control. Ratios above post-vaccination data points are the number of participants with detectable $CD4^+$ or $CD8^+$ T-cell responses within the total number of tested participants per dose group and time point.

IFN = interferon; S protein = SARS-CoV-2 sp ke protein.

Source: Interim report R-20-0244.

11.3.2 Functional and pro-inflammatory $CD4^+/CD8^+$ T-cell responses

De novo induction of SARS-CoV-2 S protein or RBD protein directed T cells was confirmed using ICS. IFNγ-producing $CD4^+$ and $CD8^+$ T cells against SARS-CoV-2 S protein or RBD were induced robustly by both BNT162b1 and BNT162b2. No clear dose dependency was observed for both IMPs. The cytokine responses elicited after dosing with either BNT162b1 or BNT162b2 in older participants was mostly identical in response pattern and intensity with that in younger participants.

BNT162b1 and BNT162 induced poly-functional and pro-inflammatory $CD4^+/CD8^+$ T-cell responses in almost all participants. The detection of IFNγ, IL-2 but not IL-4 indicates a favorable Th1 profile and the absence of a potentially deleterious Th2 immune response.

11.3.2.1 BNT162b1

As of 17 NOV 2020, evaluable functional and pro-inflammatory $CD4^+/CD8^+$ T-cell response data at baseline (before Dose 1) and at Day 29 (28 d post-Dose 1) are available for 95 study participants that received BNT162b1 (68 younger participants at dose levels of 1, 3, 10, 20, 30, 50, or 60 µg, and 27 older participants at dose levels of 10, 20, or 30 µg). This included:

- Younger participants aged 18 to 55 yrs per dose group: 1 µg (n=10), 3 µg (n=10), 10 µg (n=10), 20 µg (n=6), 30 µg (n=12), 50 µg (n=9), 60 µg (n=11).
- Older participants aged 56 to 85 yrs per dose group: 10 µg (n=8), 20 µg (n=8), 30 µg (n=11).

The functionality and polarization of vaccine-induced SARS-CoV-2 RBD-specific T cells were assessed by intracellular accumulation of the cytokines IFNγ, IL-2, and IL-4 in response to stimulation with overlapping peptides representing the full-length sequence of the vaccine-encoded RBD (amino acids [aa] 1-16 fused to aa 327-528 of the S protein) and the wild-type SARS-CoV-2 S protein by ICS. For bench-marking, PBMCs from 15 COVID-19 convalescent virologically confirmed patients were used.

Two doses of BNT162b1 (dose range 1 to 50 µg) induced cluster of differentiation 4 (CD4) and CD8 vaccine-specific T-cell responses. RBD-specific $CD4^+$ T-cell responses have a type 1 helper T (Th1) cell cytokine profile secreting IFNγ, or IL-2, or both. For 81 of the 84 analyzed participants who received both BNT162b1 doses, no production of Th2 cytokine IL-4 in response to RBD peptide pool stimulation was detected. Similarly, RBD-specific $CD8^+$ T cells secreted IFNγ in 54 of the analyzed 84 participants who received both BNT162b1 doses, however, lower levels of IL-2-secreting $CD8^+$ T cells compared to $CD4^+$ T cells were detected. In the 30 µg dose groups, the fractions of RBD-specific $IFN\gamma^+$ $CD8^+$ T cells reached up to 0.49% (younger participants) and 1.58% (older participants) of total peripheral blood $CD8^+$ T cells. In the 50 µg dose group with younger participants, fractions of up to 3.87% were detected. The mean fraction of both $CD4^+$ and $CD8^+$ cytokine-producing T cells in the BNT162b1-dosed participants (1 to 50 µg) was substantially higher (e.g., for participants dosed at 30 µg, 11-fold higher) than that observed in 15 patients who recovered from COVID-19. In the 60 µg dose group, treated with Dose 1 only, mean fractions of cytokine-producing T cells were lower compared to the other dose groups, indicating the importance of the booster vaccination. Importantly, the cytokine responses

elicited after dosing with BNT162b1 in older participants was similar in response pattern and intensity with that of the younger participants.

BNT162b1 induced poly-functional and pro-inflammatory $CD4^+/CD8^+$ T-cell responses in almost all participants, with a Th1 polarization of the helper response. The detection of IFNγ, IL-2 but not IL-4 indicates a favorable Th1 profile and the absence of a potentially deleterious Th2 immune response.

The methodology used to assess the BNT162b1 elicited antigen-specific $CD8^+$ and $CD4^+$ T-cell responses in samples from study participants dosed with BNT162b1 and complete results are presented in the interim report R-20-0235.

11.3.2.2 BNT162b2

As of 02 MAR 2021, evaluable functional and pro-inflammatory $CD4^+/CD8^+$ T-cell response data at baseline (before Dose 1) and at Day 29 (28 d post-Dose 1) are available for 79 study participants that received BNT162b2 (50 younger participants at dose levels of 1, 3, 10, 20, or 30 µg, and 29 older participants at dose levels of 10, 20, or 30 µg). This included:

- Younger participants aged 18 to 55 yrs per dose group: 1 µg (n=8), 3 µg (n=9), 10 µg (n=11), 20 µg (n=11), and 30 µg (n=11).
- Older participants 56 to 85 yrs per dose group: 10 µg (n=11), 20 µg (n=9), and 30 µg (n=9).

The functionality and polarization of vaccine-induced SARS-CoV-2 S-specific T cells were assessed by intracellular accumulation of cytokines IFNγ, IL-2, and IL-4 in response to stimulation with overlapping peptides representing the full-length sequence of the vaccine-encoded RBD and the wild-type SARS-CoV-2 S protein. For bench-marking, PBMCs from 18 virologically confirmed, convalescent COVID-19 patients were used.

To assess the persistence of cell-mediated immune responses, of 02 MAR 2021, evaluable functional and pro-inflammatory $CD4^+/CD8^+$ T-cell response data at Days 43, 85, and 184 (i.e., 3, 9, and 23 wks post-Dose 2, respectively) are also available for 41 study participants that received BNT162b2 (23 younger participants at dose levels of 10, 20, or 30 µg, and 18 older participants at dose levels of 10, 20, or 30 µg). This included:

- Younger participants aged 18 to 55 yrs per dose group: 10 µg (n=2), 20 µg (n=11), and 30 µg (n=10).
- Older participants 56 to 85 yrs per dose group: 10 µg: (n=4), 20 µg (n=7), and 30 µg (n=7).

Two doses of BNT162b2 (dose range 1 to 30 µg), induced vaccine-specific T-cell responses in both age groups analyzed at Day 29 (Figure 17 and Figure 18). Testing for SARS-CoV-2 S protein-specific T-cell responses was performed with two different peptide pools – S pool 1 comprising overlapping peptides from the N-terminal region of the S protein (which is not equivalent to structural domains) and S pool 2 comprising C-terminal regions of the S protein. S-specific $CD4^+$ T-cell responses analyzed in

79 participants dosed with BNT162b2 are characterized by a Th1 cytokine profile secreting IFNγ, or IL-2, or both at Day 29.

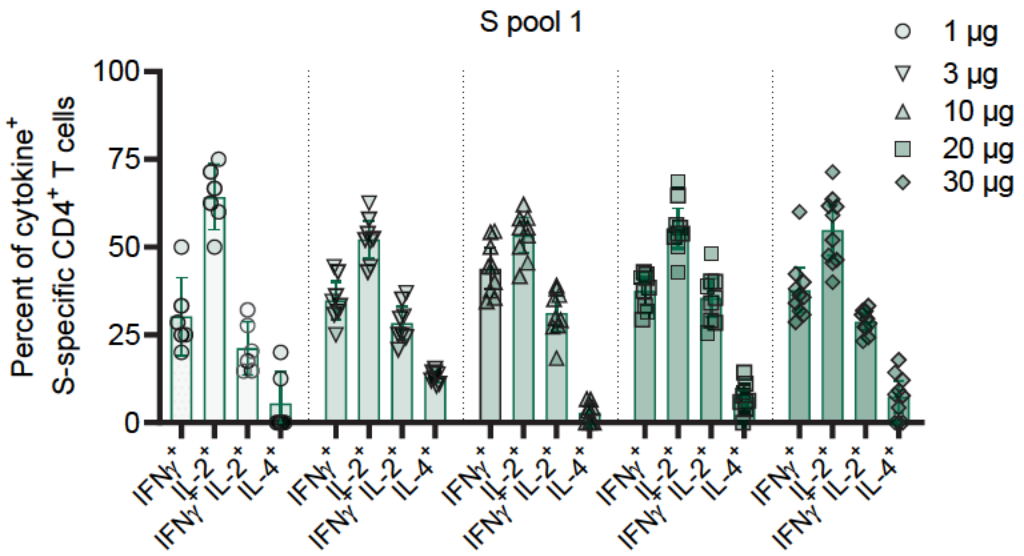

Figure 17: S-specific CD4⁺ T-cells producing the indicated cytokines in response to S protein pool 1 as a fraction of total cytokine-producing S-specific CD4⁺ T cells (1 to 30 µg BNT162b2 younger participant dose groups)

Bar charts show arithmetic means with 95% confidence interval at Day 29 (7 d after Dose 2). Cytokine production was calculated by summing up the fractions of all CD4⁺ T cells positive for either IFNγ, IL-2, or IL-4, setting this sum to 100%, and calculating the fraction of each specific cytokine-producing subset thereof. Two participants from the 1 µg dose group, 1 participant from the 3 µg dose group, and 1 participant from the 10 µg dose group were excluded from this analysis (frequency of total cytokine-producing CD4⁺ T cells <0.03%).

IFN = interferon; IL = interleukin; younger participants = participants aged 18 to 55 yrs; S protein = SARS-CoV-2 spike protein.

Source: Interim report R-20-0241.

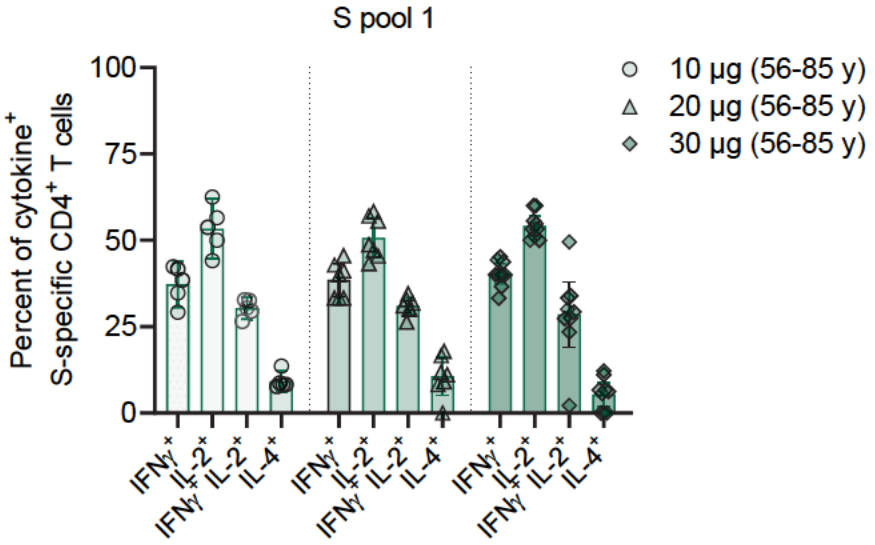

Figure 18: S-specific CD4⁺ T-cells producing the indicated cytokines in response to S protein pool 1 as a fraction of total cytokine-producing S-specific CD4⁺ T cells (10 to 30 µg BNT162b2 older participant dose groups)

Bar charts show arithmetic means with 95% CI at Day 29 (7 d after Dose 2). Cytokine production was calculated by summing up the fractions of all CD4⁺ T cells positive for either IFNγ, IL-2, or IL-4, setting this sum to 100%, and calculating the fraction of each specific cytokine-producing subset thereof. Four participants from the 10 µg dose group and 1 participant from the 20 µg dose group were excluded from this analysis (frequency of total cytokine-producing CD4⁺ T cells <0.03%).

IFN = interferon; IL = interleukin; older participants = participants aged 56 to 85 yrs; S protein = SARS-CoV-2 sp ke protein.

Source: Interim report R-20-0241.

Almost no Th2 cytokine IL-4 secreting T cells were detectable in response to S peptide sub-pool stimulations (mean fractions: 0.01% and 0.02% of antigen-specific circulating CD4⁺ T cells in the 20 and 30 µg adult dose group, respectively; separate stimulation with S protein sub-pool 1 and sub-pool 2). S-specific CD8⁺ T cells secreted IFNγ in 65 of the 79 analyzed participants at Day 29 (43 of 50 younger participants and 22 of 29 older participants) and also IL-2 secreting CD8⁺ T cells were detectable. Fractions of S-specific IFNγ⁺ CD8⁺ T cells targeting the N-terminal domain of the S protein reached up to 1.24% of total peripheral blood CD8⁺ T cells in the 20 and 30 µg younger participant dose groups and up to 1.57% in the 30 µg older participant dose group on Day 29. Pre-existing CD8⁺ T-cell responses against the C-terminal region of the S protein were detected in 17 of 79 dosed participants (range: 0.07 to 5.59% IFNγ-producing CD8⁺ T cells). In 5 of 17 participants, these pre-existing responses were slightly amplified upon BNT162b2 dosing.

Overall, the mean fractions of S-specific CD4⁺ and CD8⁺ T cells were substantially higher at Day 29 (e.g., the S protein pool 1 IFNγ CD8⁺ response of 30 µg dosed participants was 12.5-fold higher) than that observed in 18 patients who recovered from COVID-19. Importantly, for the clinically targeted 30 µg dose group, the cytokine responses elicited after vaccination with BNT162b2 in older participants was mostly identical in response pattern and intensity with that of the younger participants.

For the majority of participants, the strong S-specific IFNγ⁺ and IL-2⁺CD8⁺ and Th1 CD4⁺ T-cell responses contracted by Day 43 (3 wks post-Dose 2) and plateaued at a lower level

towards Day 85 (63 d post-Dose 2). This observation held true for all dose groups analyzed with varying response magnitudes between individuals. For the younger participants, the cell-mediated immune responses remained detectable until Day 184 (162 d post-Dose 2). Day 184 PBMC material from the older participants was not yet available at the time of this interim report. The impact of a SARS-CoV-2 infection on the persistence of vaccine-induced immune responses cannot be evaluated since the participants were not monitored for an infection on a regular basis during the course of this study.

For persistence of S-specific $CD4^+$ and $CD8^+$ T cells producing the indicated cytokines (IFNγ and IL-2) as a fraction of total circulating $CD4^+$ and $CD8^+$ T cells see Figure 19. This figure shows the data for the 30 µg BNT162b2 dose group in younger and older participants and is considered representative of what is seen for other dose groups. For details of what is seen for other dose groups, see the interim report R-20-0241.

BNT162b2-induced T-cell responses, especially for $CD8^+$ T cells, were not limited to the RBD, and pronounced and strong T cell recognition of non-RBD regions of the S protein were observed indicating a polyvalent immune recognition of multiple independent MHC I and II epitopes across the entire S protein.

BNT162b2 induced poly-functional and pro-inflammatory $CD4^+$/$CD8^+$ T-cell responses in almost all participants persisting in the majority of participants for up to 6 months after Dose 1. The Th1 polarization of the helper T-cell response was characterized by a robust IFNγ/IL-2 and only minor IL-4 production upon antigen-specific (wild-type SARS-CoV-2 S protein peptide pools) re-stimulation which was still observed, although with a reduced magnitude, at later time points.

The methodology used to assess the BNT162b2 elicited antigen-specific $CD8^+$ and $CD4^+$ T-cell responses in samples from study participants dosed with BNT162b2 and complete results are presented in the interim report R-20-0241.

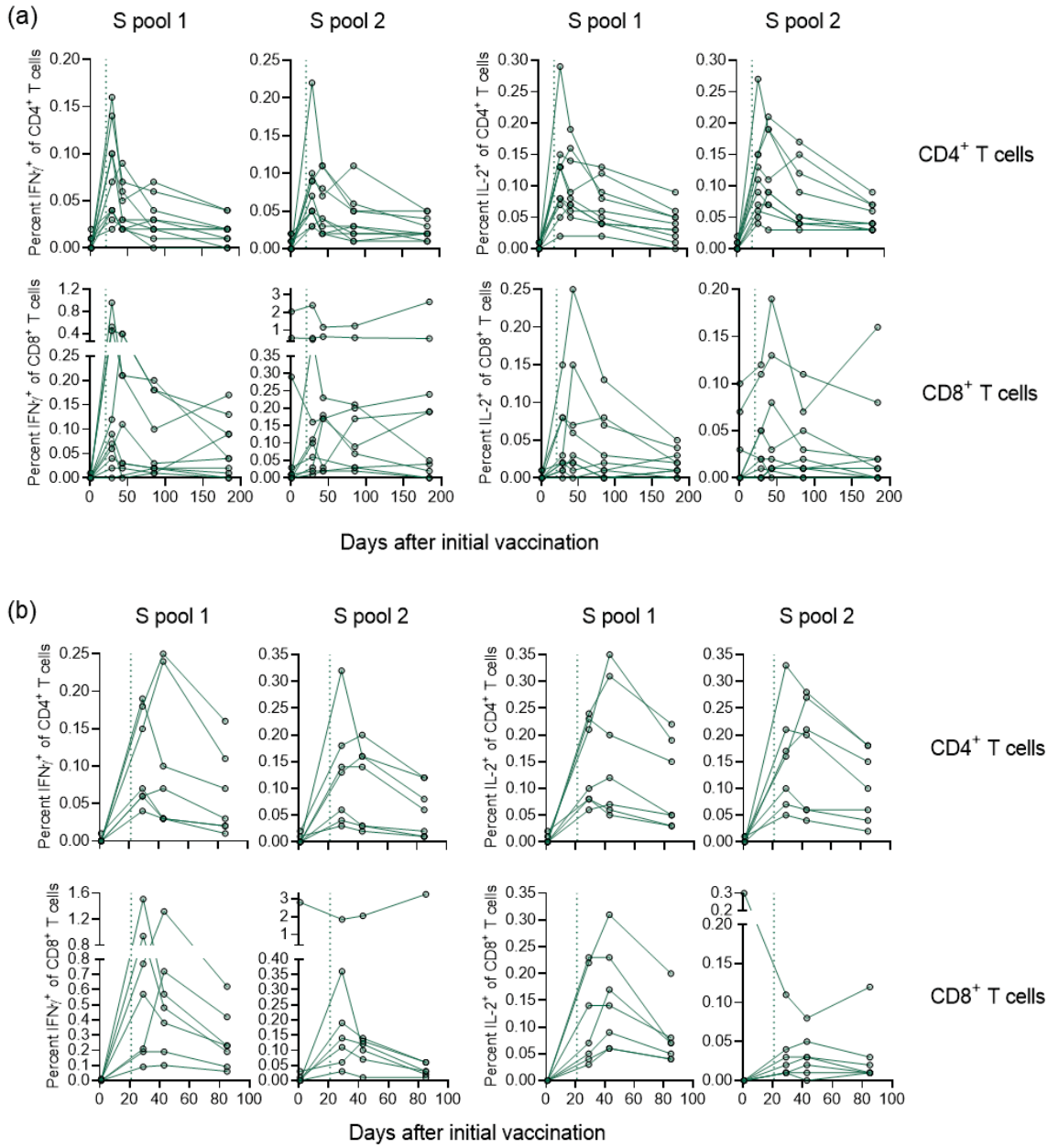

Figure 19: Persistence of S-specific CD4+ and CD8+ T cells producing the indicated cytokines (IFNγ and IL-2) as a fraction of total circulating CD4+ and CD8+ T cells (30 µg BNT162b2 dose group in younger and older participants)

Cytokine data are plotted for participants from (a) the 30 µg dose group in younger participants (aged 18 to 55 yrs, n=10) and (b) 30 µg dose group in older participants (aged 56 to 85 yrs, n=7) from Day 1 (before Dose 1), Day 29 (7 d post-Dose 2), Day 43 (3 wks post-Dose 2), Day 85 (9 wks post-Dose 2) and Day 184 (23 wks post-Dose 2, (a) only) after Dose 1. Green dotted lines indicate the time point of Dose 2 (Day 22).

IFN = interferon; IL = interleukin.

Source: Interim report R-20-0241.

11.4 Genetics

No genetics data was available at the cut-off date for this report.

12 SAFETY EVALUATION

12.1 Extent of exposure

For the extent of exposure to BNT162b1 and BNT162b2 at the data cut-off date for reactogenicity and safety for younger and older participants, see Table 16. The IMP exposure by participant is given in Listing 16.2.3-2.1-1 (BNT162b1) and Listing 16.2.3-2.1-3 (BNT162b2). For BNT162b1, Dose 2 in the 60 µg group was omitted due to the SRC decision.

Table 16: Extent of exposure to BNT162b1 and BNT162b2

IMP	Dose group	Number of participants given Dose 1	Number of participants given Dose 2
BNT162b1	1 µg younger participants	12	12
	3 µg younger participants	12	12
	10 µg younger participants	12	11
	20 µg younger participants	12	11
	30 µg younger participants	12	12
	50 µg younger participants	12	11
	60 µg younger participants	12	0
	10 µg older participants	12	12
	20 µg older participants	12	11
	30 µg older participants	12	12
BNT162b2	1 µg younger participants	12	11
	3 µg younger participants	12	12
	10 µg younger participants	12	11
	20 µg younger participants	12	12
	30 µg younger participants	12	12
	10 µg older participants	12	12
	20 µg older participants	12	12
	30 µg older participants	12	12

IMP = investigational medicinal product.
Source: Tables 14.3.2-1.1-1 and 14.3.2-1.1-3, Listings 16.2.3-2.1-1 and 16.2.3-2.1-3.

12.2 Primary safety endpoints

12.2.1 BNT162b1

12.2.1.1 Younger participants

A total of 72 participants (86%) reported solicited local reactions, of which 15 participants (18%) reported Grade ≥3 solicited local reactions. A total of 77 participants (92%) reported solicited systemic reactions, of which 37 participants (44%) reported Grade ≥3 solicited systemic reactions.

A total of 38 participants (45%) reported in total 83 TEAEs, of which 51 were related TEAEs. Two participants (2%) reported Grade ≥3 TEAEs of which three events were assessed as related by the investigator.

There were no TESAEs or deaths. One AE (8%) led to discontinuation.

There were no TEAEs of special interest (TEAE-SI).

Table 17 provides an overview of younger participants with solicited reactogenicity events or unsolicited TEAEs.

Table 17: An overview of primary endpoint – BNT162b1 (SAF)

	Younger participants							
Participants with at least one	**1 µg (N=12)**	**3 µg (N=12)**	**10 µg (N=12)**	**20 µg (N=12)**	**30 µg (N=12)**	**50 µg (N=12)**	**60 µg (N=12)**	**Total (N=84)**
Any solicited local reaction n (%)	7 (58)	6 (50)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	72 (86)
Any grade >= 3 local reaction n (%)	2 (17)	0 (0)	1 (8)	2 (17)	5 (42)	4 (33)	1 (8)	15 (18)
Any systemic reaction n (%)	11 (92)	9 (75)	10 (83)	11 (92)	12 (100)	12 (100)	12 (100)	77 (92)
Any grade >= 3 systemic reaction n (%)	3 (25)	1 (8)	6 (50)	5 (42)	6 (50)	8 (67)	8 (67)	37 (44)
Any TEAE n (%) E	6 (50) 21	0 (0) 0	7 (58) 16	5 (42) 12	6 (50) 8	8 (67) 17	6 (50) 9	38 (45) 83
Related TEAE n (%) E	4 (33) 10	0 (0) 0	6 (50) 10	4 (33) 9	4 (33) 4	6 (50) 10	6 (50) 8	30 (36) 51
Grade >= 3 TEAE n (%) E	0 (0) 0	0 (0) 0	0 (0) 0	2 (17) 4	0 (0) 0	0 (0) 0	0 (0) 0	2 (2) 4
Related grade >= 3 TEAE n (%) E	0 (0) 0	0 (0) 0	0 (0) 0	1 (8) 3	0 (0) 0	0 (0) 0	0 (0) 0	1 (1) 3
Any TESAE n (%) E	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Related TESAE n (%) E	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Death n (%) E	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
AEs leading to discontinuation n (%) E	0 (0) 0	0 (0) 0	1 (8) 1	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	1 (1) 1
TEAE-SI n (%) E	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

	Older participants				All Total (N=120)
Participants with at least one	**10 µg (N=12)**	**20 µg (N=12)**	**30 µg (N=12)**	**Total (N=36)**	
Any solicited local reaction n (%)	8 (67)	11 (92)	11 (92)	30 (83)	102 (85)
Any grade >= 3 local reaction n (%)	0 (0)	0 (0)	0 (0)	0 (0)	15 (13)
Any systemic reaction n (%)	9 (75)	12 (100)	12 (100)	33 (92)	110 (92)
Any grade >= 3 systemic reaction n (%)	2 (17)	3 (25)	5 (42)	10 (28)	47 (39)
Any TEAE n (%) E	3 (25) 3	2 (17) 4	8 (67) 17	13 (36) 24	51 (43) 107
Related TEAE n (%) E	0 (0) 0	0 (0) 0	5 (42) 9	5 (14) 9	35 (29) 60
Grade >= 3 TEAE n (%) E	1 (8) 1	1 (8) 1	2 (17) 2	4 (11) 4	6 (5) 8
Related grade >= 3 TEAE n (%) E	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	2 (2) 4
Any TESAE n (%) E	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
Related TESAE n (%) E	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Death n (%) E	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
AEs leading to discontinuation n (%) E	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	1 (1) 1
TEAE-SI n (%) E	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

All = all is the sum of younger and older participants; AE = adverse event; E = number of events; n = number of participants with the specified characteristic; N = total number of participants; SAF = Safety Set; TEAE = treatment-emergent adverse event; TESAE = treatment-emergent serious adverse event; TEAE-SI = TEAE of special interest.

Source: Tables 14.3.1-1.1-1, 14.3.1-2.1-1, 14.3.1-3.1.3-1, 14.3.1-3.2.5-1, 14.3.1-3.2.6-1, 14.3.1-3.2.7-1, and 14.3.1-3.1.4-1, Listing 16.2.1-3-1.

12.2.1.2 Older participants and all (younger and older) participants

A total of 30 participants (83%) reported solicited local reactions, of which none of the participants reported Grade ≥3 solicited local reactions. A total of 33 participants (92%) reported solicited systemic reactions, of which 10 participants (28%) reported Grade ≥3 solicited systemic reactions.

A total of 13 participants (36%) reported in total 24 TEAEs, of which 9 events were related TEAEs. Four participants (11%) reported Grade ≥3 TEAEs of which one event was assessed as related by the investigator.

There were no deaths and one participant had a TESAE (syncope).

There were no TEAEs of special interest (TEAE-SI).

Table 17 provides an overview of older participants with solicited reactogenicity events or unsolicited TEAEs.

For both the younger and older participants, there was a clear dose relationship for solicited local reactions and for systemic reactions.

12.2.2 BNT162b2

12.2.2.1 Younger participants

A total of 52 participants (87%) reported solicited local reactions. A total of 53 participants (88%) reported solicited systemic reactions, of which 6 participants (10%) reported Grade ≥3 solicited systemic reactions.

A total of 26 participants (43%) reported in total 51 TEAEs, of which 6 events were related TEAEs. One participant (2%) reported a Grade ≥3 TEAE which was assessed as not related by the investigator.

There were no TESAEs or deaths. One AE (moderate nasopharyngitis) led to discontinuation.

There were no TEAEs of special interest (TEAE-SI). TEAE-SI are defined as: Enhanced respiratory disease or flu-like symptomatology not resolved after 7 d or with symptom kinetics that are inconsistent with a relationship to RNA immunization.

Table 18 provides an overview of younger participants with solicited reactogenicity events or unsolicited TEAEs.

12.2.2.2 Older participants and all (younger and older) participants

A total of 31 participants (86%) reported solicited local reactions, of which 2 participants (6%) reported Grade ≥3 solicited local reactions. A total of 26 participants (72%) reported solicited systemic reactions, of which 4 participants (11%) reported Grade ≥3 solicited systemic reactions.

A total of 12 participants (33%) reported in total 20 TEAEs, of which 2 events were related TEAEs. Three participants (8%) reported Grade ≥3 TEAEs of which one event was assessed as related by the investigator.

There were no deaths and one participant had a not related TESAE (ankle fracture).

There were no TEAEs of special interest (TEAE-SI).

Table 18 provides an overview of older participants with solicited reactogenicity events or unsolicited TEAEs.

Table 18: An overview of primary endpoint – BNT162b2 (SAF)

Participants with at least one	Younger participants					
	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Any solicited local reaction n (%)	7 (58)	10 (83)	12 (100)	12 (100)	11 (92)	52 (87)
Any grade >= 3 local reaction n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Any systemic reaction n (%)	9 (75)	9 (75)	12 (100)	11 (92)	12 (100)	53 (88)
Any grade >= 3 systemic reaction n (%)	0 (0)	0 (0)	1 (8)	2 (17)	3 (25)	6 (10)
Any TEAE n (%) E	5 (42) 7	7 (58) 22	7 (58) 11	2 (17) 3	5 (42) 8	26 (43) 51
Related TEAE n (%) E	1 (8) 1	2 (17) 2	1 (8) 1	1 (8) 2	1 (8) 3	6 (10) 9
Grade >=3 TEAE n (%) E	0 (0) 0	0 (0) 0	1 (8) 1	0 (0) 0	0 (0) 0	1 (2) 1
Related grade >=3 TEAE n (%) E	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Any TESAE n (%) E	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Related TESAE n (%) E	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Death n (%) E	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
AEs leading to discontinuation n (%) E	0 (0) 0	0 (0) 0	1 (8) 1	0 (0) 0	0 (0) 0	1 (2) 1
TEAE-SI n (%) E	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

Participants with at least one	Older participants				All Total (N=96)
	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	
Any solicited local reaction n (%)	9 (75)	11 (92)	11 (92)	31 (86)	83 (86)
Any grade >= 3 local reaction n (%)	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
Any systemic reaction n (%)	5 (42)	10 (83)	11 (92)	26 (72)	79 (82)
Any grade >= 3 systemic reaction n (%)	2 (17)	0 (0)	2 (17)	4 (11)	10 (10)
Any TEAE n (%) E	3 (25) 5	6 (50) 9	3 (25) 6	12 (33) 20	38 (40) 71
Related TEAE n (%) E	1 (8) 3	0 (0) 0	1 (8) 1	2 (6) 4	8 (8) 13
Grade >=3 TEAE n (%) E	0 (0) 0	1 (8) 1	2 (17) 2	3 (8) 3	4 (4) 4
Related grade >=3 TEAE n (%) E	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
Any TESAE n (%) E	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
Related TESAE n (%) E	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Death n (%) E	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
AEs leading to discontinuation n (%) E	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	1 (1) 1
TEAE-SI n (%) E	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

All = all is the sum of younger and older participants; AE = adverse event; E = number of events; n = number of participants with the specified characteristic; N = total number of participants; SAF = Safety Set; TEAE = treatment-emergent adverse event; TESAE = treatment-emergent serious adverse event; TEAE-SI = TEAE of special interest.

Source: Tables 14.3.1-1.1-3, 14.3.1-2.1-3, 14.3.1-3.1.3-3, 14.3.1-3.2.5-3, 14.3.1-3.2.6-3, 14.3.1-3.2.7-3, and 14.3.1-3.1.4-3, Listing 16.2.1-3-3.

12.3 Solicited local reactions

12.3.1 Solicited local reactions within 7 d after each BNT162b1 dose

A summary of solicited local reactions is presented in Table 19. All solicited local reaction data by participant is given in Listing 16.2.3-1.1-1.

12.3.1.1 Younger participants

Within 7 d after Dose 1;

- 81% of the younger participants reported at least one local reaction of any grade on at least one occasion.
- In total 10 younger participants reported Grade ≥3 local reactions.
- In the younger participants group, a possible dose dependency for Grade ≥3 local reactions between the 10 µg group (1 participant) and the 20 µg and 30 µg groups (2 and 4 participants) was seen.

Within 7 d after Dose 2;

- 80% of the younger participants reported at least one local reaction of any grade on at least one occasion.
- In total 7 younger participants reported Grade ≥3 local reactions.
- In the younger participants group, a possible dose dependency for Grade ≥3 local reactions between the 10 µg group (0 participants) and the 30 µg and 50 µg groups (2 and 3 participants) was seen. The Dose 2 in the 60 µg group was omitted due to the SRC decision.

Across the two intervals combined, 72 participants (86%) in the younger participants group reported any local reaction at any dose, of which 15 (18%) participants reported a Grade ≥3 local reaction with a possible dose dependency between 10 µg (1 participant) and 20 µg and 30 µg (2 and 5 participants) doses.

12.3.1.2 Older participants

Within 7 d after Dose 1;

- 81% of the older participants reported at least one local reaction of any grade on at least one occasion.
- No older participants reported Grade ≥3 local reactions.
- A possible dose dependency for local reactions between the 10 µg group (7 participants) and the 20 µg and 30 µg groups (11 participants) was seen.

Within 7 d after Dose 2;

- 74% of the older participants reported at least one local reaction of any grade on at least one occasion.
- No participants in the older participants group reported Grade ≥3 local reactions.

Across the two intervals combined, 30 participants (83%) reported any local reaction at any dose in the combined interval. No participants reported Grade ≥3 local reactions.

Table 19: Summary of solicited local reactions – BNT162b1 (SAF)

Time interval		Younger participants							
		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Dose 1 up to Day 7 after Dose 1	nn	12	12	12	12	12	12	12	84
	Any local reaction n (%)	6 (50)	5 (42)	10 (83)	12 (100)	11 (92)	12 (100)	12 (100)	68 (81)
	Any grade >= 3 local reaction n (%)	0 (0)	0 (0)	1 (8)	2 (17)	4 (33)	2 (17)	1 (8)	10 (12)
Dose 2 up to Day 7 after Dose 2	nn	12	6	11	10	12	11	N/A	69
	Any local reaction n (%)	7 (58)	5 (42)	10 (91)	11 (100)	11 (92)	11 (100)	N/A	55 (80)
	Any grade >= 3 local reaction n (%)	2 (17)	0 (0)	0 (0)	0 (0)	2 (17)	3 (27)	N/A	7 (10)
Combined interval	nn	12	12	12	12	12	12	12	84
	Any local reaction n (%)	7 (58)	6 (50)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	72 (86)
	Any grade >= 3 local reaction n (%)	2 (17)	0 (0)	1 (8)	2 (17)	5 (42)	4 (33)	1 (8)	15 (18)

Time interval		Older participants				All Total (N=120)
		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	
Dose 1 up to Day 7 after Dose 1	nn	12	12	12	36	120
	Any local reaction n (%)	7 (58)	11 (92)	11 (92)	29 (81)	97 (81)
	Any grade >= 3 local reaction n (%)	0 (0)	0 (0)	0 (0)	0 (0)	10 (8)
Dose 2 up to Day 7 after Dose 2	nn	12	11	12	35	104
	Any local reaction n (%)	8 (67)	9 (82)	9 (75)	26 (74)	81 (78)
	Any grade >= 3 local reaction n (%)	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
Combined interval	nn	12	12	12	36	120
	Any local reaction n (%)	8 (67)	11 (92)	11 (92)	30 (83)	102 (85)
	Any grade >= 3 local reaction n (%)	0 (0)	0 (0)	0 (0)	0 (0)	15 (13)

The combined interval is the union of the intervals 'Dose 1 up to Day 7 after Dose 1' and 'Dose 2 up to Day 7 after Dose 2'. The denominator for the percentage calculation is nn.

All = all is the sum of younger and older participants; N = number of participants in the analysis set; n = number of participants with the respective local reactions; nn = number of participants with any information on local reactions available; N/A = not available, SAF = Safety Set.

Source: Table 14.3.1-1.1-1.

12.3.2 Local reactions by severity – BNT162b1

An overview of solicited local reactions by severity is given below in Table 20. The frequency of participants with solicited local reactions by term per day is presented in Table 14.3.1-1.6.2-1.

12.3.2.1 Younger participants

In the younger participants group, in the combined time interval, after both doses, the majority of the participants experienced mild (n=72, 86%) followed by moderate (n=45,

54%) solicited local reactions. While few participants experienced severe (n=15, 18%) solicited local reactions.

- The most frequent severe solicited local reactions were reported in 30 µg (5 participants [42%]), 50 µg (4 participants [33%]), 20 µg (2 participants [17%]), 60 µg (1 participant [8%]), and 10 µg (1 participant [8%]) dose groups.

The most frequently reported solicited local reactions of any severity were tenderness (n=70, 83%) and pain (n=67, 80%). The remaining symptom terms were less frequent.

- Only mild and moderate reactions were reported for erythema and induration.
- For pain and tenderness each symptom was assessed as severe in ≤14% of participants.
- No clear pattern of dose dependency was seen across the symptom terms for mild reactions in 10 µg and above dose groups. However, a possible dose dependency for moderate local reactions between the 10 µg group (5 participants) and the 20 µg and 30 µg groups (6 and 11 participants) was seen.

12.3.2.2 Older participants and all (younger and older) participants

In the older participants group, in the combined time interval, after both doses, the majority of the participants experienced mild (n=30, 83%) followed by moderate (n=15, 42%) solicited local reactions, while no older participants experienced severe solicited local reactions.

The most frequently reported solicited local reactions of any severity were tenderness (n=28, 78%) and pain (n=27, 75%). The remaining symptom terms were less frequent.

- Only mild reactions were reported for erythema and induration.
- For pain and tenderness each symptom was assessed as moderate in <40% of participants.

Table 20: Frequency of participants with solicited local reactions by grade – BNT162b1 (Combined interval – SAF)

Lines with only zeros are not shown		Younger participants							
		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
	nn	12	12	12	12	12	12	12	84
Any	Any n (%)	7 (58)	6 (50)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	72 (86)
	Mild n (%)	7 (58)	6 (50)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	72 (86)
	Moderate n (%)	5 (42)	1 (8)	5 (42)	6 (50)	11 (92)	10 (83)	7 (58)	45 (54)
	Severe n (%)	2 (17)	0 (0)	1 (8)	2 (17)	5 (42)	4 (33)	1 (8)	15 (18)
Pain	Any n (%)	6 (50)	4 (33)	9 (75)	12 (100)	12 (100)	12 (100)	12 (100)	67 (80)
	Mild n (%)	5 (42)	4 (33)	9 (75)	12 (100)	12 (100)	11 (92)	12 (100)	65 (77)
	Moderate n (%)	3 (25)	1 (8)	2 (17)	5 (42)	9 (75)	8 (67)	2 (17)	30 (36)
	Severe n (%)	1 (8)	0 (0)	1 (8)	2 (17)	4 (33)	3 (25)	1 (8)	12 (14)
Tenderness	Any n (%)	7 (58)	6 (50)	11 (92)	12 (100)	11 (92)	12 (100)	11 (92)	70 (83)
	Mild n (%)	6 (50)	6 (50)	10 (83)	12 (100)	10 (83)	12 (100)	11 (92)	67 (80)
	Moderate n (%)	5 (42)	1 (8)	5 (42)	6 (50)	11 (92)	10 (83)	7 (58)	45 (54)
	Severe n (%)	2 (17)	0 (0)	1 (8)	1 (8)	4 (33)	3 (25)	0 (0)	11 (13)
Erythema / Redness	Any n (%)	0 (0)	1 (8)	0 (0)	1 (8)	3 (25)	3 (25)	0 (0)	8 (10)
	Mild n (%)	0 (0)	1 (8)	0 (0)	1 (8)	3 (25)	3 (25)	0 (0)	8 (10)
	Moderate n (%	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	0 (0)	3 (4)
Induration / Swelling	Any n (%)	2 (17)	1 (8)	1 (8)	2 (17)	2 (17)	4 (33)	1 (8)	13 (15)
	Mild n (%)	0 (0)	1 (8)	1 (8)	2 (17)	2 (17)	3 (25)	1 (8)	10 (12)
	Moderate n (%)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)

Lines with only zeros are not shown		Older participants				All Total (N=120)
		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	
	nn	12	12	12	36	120
Any	Any n (%)	8 (67)	11 (92)	11 (92)	30 (83)	102 (85)
	Mild n (%)	8 (67)	11 (92)	11 (92)	30 (83)	102 (85)
	Moderate n (%)	3 (25)	5 (42)	7 (58)	15 (42)	60 (50)
	Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	15 (13)
Pain	Any n (%)	7 (58)	10 (83)	10 (83)	27 (75)	94 (78)
	Mild n (%)	7 (58)	10 (83)	10 (83)	27 (75)	92 (77)
	Moderate n (%)	2 (17)	2 (17)	5 (42)	9 (25)	39 (33)
	Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	12 (10)
Tenderness	Any n (%)	8 (67)	10 (83)	10 (83)	28 (78)	98 (82)
	Mild n (%)	8 (67)	10 (83)	10 (83)	28 (78)	95 (79)
	Moderate n (%)	2 (17)	5 (42)	7 (58)	14 (39)	59 (49)
	Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	11 (9)
Erythema / Redness	Any n (%)	2 (17)	0 (0)	2 (17)	4 (11)	12 (10)
	Mild n (%)	2 (17)	0 (0)	2 (17)	4 (11)	12 (10)
	Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Induration / Swelling	Any n (%)	2 (17)	3 (25)	3 (25)	8 (22)	21 (18)
	Mild n (%)	2 (17)	3 (25)	3 (25)	8 (22)	18 (15)
	Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)

The combined interval is the union of the intervals 'Dose 1 up to Day 7 after Dose 1' and 'Dose 2 up to Day 7 after Dose 2'. The denominator for the percentage calculation is nn.

All = all is the sum of younger and older participants; N = number of participants in the analysis set; n = number of participants with the respective local reaction; nn = number of participants with any information on local reactions available; SAF = Safety Set.
Source: modified from Table 14.3.1-1.3-1.

12.3.3 Time to onset and duration of local reactions – BNT162b1

12.3.3.1 Younger participants

In the younger participants group, the mean time (SD) from Dose 1 to first local reaction was 1.1 d (0.4), while the mean time (SD) from first to last local reaction was 3.0 d (1.8). The mean time (SD) from Dose 1 to first Grade ≥3 local reaction was 1.5 d (0.5). The mean time (SD) from first to last Grade ≥3 local reaction was 1.2 d (0.4) (Table 14.3.1-1.5.1-1).

The mean time (SD) from Dose 2 to first local reaction was 1.1 d (0.6), while the mean time (SD) from first to last local reaction was 3.5 d (1.9). The mean time (SD) from Dose 2 to first Grade ≥3 local reaction was 1.1 d (0.4). The mean time (SD) from first to last Grade ≥3 local reaction was 1.9 d (1.2) (Table 14.3.1-1.5.1-1).

After Dose 1, for almost all participants, except for 1 (10%) for the 30 µg dose group there were no local reactions on Day 7. After Dose 2, except for 1 (10%) for the 10 µg dose group there were no local reactions on Day 7. (Table 14.3.1-1.6.1-1).

The participant's diary compliance for reporting local reactions after Dose 1 was 100% up to Day 6, while after Dose 2 it was ≥81% up to Day 5 before dropping on Days 6 and 7 in some dose groups (Table 14.3.2-1.2-1, Listing 16.2.3-1.2-1).

12.3.3.2 Older participants and all (younger and older) participants

In the older participants group, the mean time (SD) from Dose 1 to first local reaction was 1.1 d (0.3), while the mean time (SD) from first to last local reaction was 2.8 d (1.6). The mean time (SD) from Dose 1 to first Grade ≥3 local reaction was 1.5 d (0.5). The mean time (SD) from first to last Grade ≥3 local reaction was 1.2 d (0.4) (Table 14.3.1-1.5.1-1).

The mean time (SD) from Dose 2 to first local reaction was 1.1 d (0.5), while the mean time (SD) from first to last local reaction was 3.5 d (2.0). The mean time (SD) from Dose 2 to first Grade ≥3 local reaction was 1.1 d (0.4). The mean time (SD) from first to last Grade ≥3 local reaction was 1.9 d (1.2) (Table 14.3.1-1.5.1-1).

After Dose 1, there were no local reactions in any dose group after Day 5. After Dose 2, except for 1 (11%) for the 20 µg dose group there were no local reactions on Day 7. (Table 14.3.1-1.6.1-1).

The participant's diary compliance for reporting local reactions after Dose 1 was ≥99% up to Day 6, while after Dose 2 it was ≥86% up to Day 5 before dropping on Days 6 and 7 in some dose groups (Table 14.3.2-1.2-1, Listing 16.2.3-1.2-1).

Descriptive statistics of time of solicited local and any solicited reactions by term is presented in Table 14.3.1-1.5.2-1. A summary of solicited local reactions reported by participants (who completed doses 1 and 2) within 7 d after each dose is presented in Table 14.3.1-1.2-1. An overview of solicited local reactions by severity reported by

participants (who completed doses 1 and 2) within 7 d after each dose is presented in Table 14.3.1-1.4-1.

12.3.4 Solicited local reactions within 7 d after each BNT162b2 dose

A summary of solicited local reactions is presented in Table 21. All solicited local reaction data by participant is given in Listing 16.2.3-1.1-3.

12.3.4.1 Younger participants

Within 7 d after Dose 1;

- A total of 82% of participants reported at least one local reaction of any grade on at least one occasion.
- None of the participants reported Grade ≥3 local reactions.

Within 7 d after Dose 2;

- A total of 74% of participants reported at least one local reaction of any grade on at least one occasion.
- None of the participants reported Grade ≥3 local reactions.

Across the 2 intervals combined, 52 participants (87%) reported any local reaction at any dose, of which none of the participants reported Grade ≥3 local reactions.

12.3.4.2 Older participants and all (younger and older) participants

Within 7 d after Dose 1;

- A total of 69% of participants reported at least one local reaction of any grade on at least one occasion.
- None of the participants reported Grade ≥3 local reactions.

Within 7 d after Dose 2;

- A total of 69% of participants reported at least one local reaction of any grade on at least one occasion.
- Grade ≥3 local reactions were reported by 2 participants (6%).

Across the 2 intervals combined, 31 participants (86%) reported any local reaction at any dose, of which 2 participants (6%) reported Grade ≥3 local reactions.

Table 21: Summary of solicited local reactions – BNT162b2 (SAF)

Time interval		Younger participants					
		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Dose 1 up to Day 7 after Dose 1	nn	12	12	12	12	12	60
	Any local reaction n (%)	6 (50)	9 (75)	12 (100)	12 (100)	10 (83)	49 (82)
	Any grade >= 3 local reaction n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dose 2 up to Day 7 after Dose 2	nn	11	12	11	12	12	58
	Any local reaction n (%)	4 (36)	8 (67)	10 (91)	10 (83)	11 (92)	43 (74)
	Any grade >= 3 local reaction n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Combined interval	nn	12	12	12	12	12	60
	Any local reaction n (%)	7 (58)	10 (83)	12 (100)	12 (100)	11 (92)	52 (87)
	Any grade >= 3 local reaction n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Time interval		Older participants				All Total (N=96)
		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	
Dose 1 up to Day 7 after Dose 1	nn	12	12	12	36	96
	Any local reaction n (%)	7 (58)	9 (75)	9 (75)	25 (69)	74 (77)
	Any grade >= 3 local reaction n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dose 2 up to Day 7 after dose 2	nn	12	12	12	36	94
	Any local reaction n (%)	7 (58)	8 (67)	10 (83)	25 (69)	68 (72)
	Any grade >= 3 local reaction n (%)	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
Combined interval	nn	12	12	12	36	96
	Any local reaction n (%)	9 (75)	11 (92)	11 (92)	31 (86)	83 (86)
	Any grade >= 3 local reaction n (%)	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)

The combined interval is the union of the intervals 'Dose 1 up to Day 7 after Dose 1' and 'Dose 2 up to Day 7 after Dose 2'. The denominator for the percentage calculation is nn.

All = all is the sum of younger and older participants; N = number of participants in the analysis set; n = number of participants with the respective local reactions; nn = number of participants with any information on local reactions available; SAF = Safety Set.

Source: Table 14.3.1-1.1-3.

12.3.5 Local reactions by severity – BNT162b2

An overview of solicited local reactions by severity is given below in Table 22. The frequency of participants with solicited local reactions by term per day is presented in Table 14.3.1-1.6.2-3.

12.3.5.1 Younger participants

In younger participants, in the combined time interval, after both doses, the majority of the participants experienced mild (n=52, 87%) solicited local reactions. A few participants experienced moderate (n=21, 35%) solicited local reactions.

- The most frequent, moderate grade solicited local reactions were reported in 10 µg and 20 µg (7 participants each [58%], respectively) dose groups, followed by 30 µg (3 participants [25%]) dose group.

- The most frequently reported solicited local reactions of any severity was mild tenderness (n=45, 75%) and mild pain (n=45, 75%). The remaining symptom terms were less frequent.
- Only mild reactions were reported for erythema and induration.
- Pain was assessed as moderate in ≤10% of participants.
- No clear pattern of dose dependency was seen across the symptom terms for mild or moderate reactions.

12.3.5.2 Older participants and all (younger and older) participants

In older participants, in the combined time interval, after both doses, the majority of the participants experienced mild (n=28, 78%) solicited local reactions. A few participants experienced moderate (n=13, 36%) solicited local reactions.

- The most frequent, moderate grade solicited local reactions were reported in 30 µg (n=6, 50%) followed by 20 µg (n=4, 33%) and 10 µg (n=3, 25%) dose groups.
- The most frequently reported solicited local reactions of any severity was mild tenderness (n=24, 67%) followed by mild pain (n=22, 61%). The remaining symptom terms were less frequent.
- One participant had a moderate reaction of erythema and only mild reactions were reported for induration.
- Pain was assessed as moderate in ≤14% of participants.
- No clear pattern of dose dependency was seen across the symptom terms for mild or moderate reactions.

Table 22: Frequency of participants with solicited local reactions by grade – BNT162b2 (Combined interval – SAF)

Note: lines with only zero values are not shown		Younger participants					
		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
	nn	12	12	12	12	12	60
Any	Any n (%)	7 (58)	10 (83)	12 (100)	12 (100)	11 (92)	52 (87)
	Mild n (%)	7 (58)	10 (83)	12 (100)	12 (100)	11 (92)	52 (87)
	Moderate n (%)	2 (17)	2 (17)	7 (58)	7 (58)	3 (25)	21 (35)
Pain	Any n (%)	5 (42)	6 (50)	12 (100)	12 (100)	10 (83)	45 (75)
	Mild n (%)	5 (42)	6 (50)	12 (100)	12 (100)	10 (83)	45 (75)
	Moderate n (%)	0 (0)	(0)	1 (8)	4 (33)	1 (8)	6 (10)
Tenderness	Any n (%)	5 (42)	10 (83)	12 (100)	10 (83)	11 (92)	48 (80)
	Mild n (%)	5 (42)	10 (83)	9 (75)	10 (83)	11 (92)	45 (75)
	Moderate n (%)	2 (17)	2 (17)	7 (58)	6 (50)	3 (25)	20 (33)
Erythema/ Redness	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
	Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Induration/ Swelling	Any n (%)	0 (0)	0 (0)	1 (8)	0 (0)	3 (25)	4 (7)
	Mild n (%)	0 (0)	0 (0)	1 (8)	0 (0)	3 (25)	4 (7)

Note: lines with only zero values are not shown		Older participants				All Total (N=96)
		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	
	nn	12	12	12	36	96
Any	Any n (%)	9 (75)	11 (92)	11 (92)	31 (86)	83 (86)
	Mild n (%)	7 (58)	11 (92)	10 (83)	28 (78)	80 (83)
	Moderate n (%)	3 (25)	4 (33)	6 (50)	13 (36)	34 (35)
	Severe n (%)	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
Pain	Any n (%)	4 (33)	9 (75)	11 (92)	24 (67)	69 (72)
	Mild n (%)	3 (25)	9 (75)	10 (83)	22 (61)	67 (70)
	Moderate n (%)	0 (0)	1 (8)	4 (33)	5 (14)	11 (11)
	Severe n (%)	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
Tenderness	Any n (%)	8 (67)	9 (75)	9 (75)	26 (72)	74 (77)
	Mild n (%)	6 (50)	9 (75)	9 (75)	24 (67)	69 (72)
	Moderate n (%)	3 (25)	4 (33)	4 (33)	11 (31)	31 (32)
Erythema/Redness	Any n (%)	2 (17)	1 (8)	2 (17)	5 (14)	6 (6)
	Mild n (%)	1 (8)	1 (8)	2 (17)	4 (11)	5 (5)
	Moderate n (%)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Induration/Swelling	Any n (%)	2 (17)	1 (8)	1 (8)	4 (11)	8 (8)
	Mild n (%)	2 (17)	1 (8)	1 (8)	4 (11)	8 (8)

The combined interval is the union of the intervals 'Dose 1 up to Day 7 after Dose 1' and 'Dose 2 up to Day 7 after Dose 2'. The denominator for the percentage calculation is nn.

All = all is the sum of younger and older participants; N = number of participants in the analysis set; n = number of participants with the respective local reaction; nn = number of participants with any information on local reactions available; SAF = Safety Set.

Source: modified from Table 14.3.1-1.3-3.

12.3.6 Time to onset and duration of local reactions – BNT162b2

12.3.6.1 Younger participants

The mean time (SD) from Dose 1 to first local reaction was 1.1 d (0.3), while the mean time (SD) from first local reaction to last local reaction was 2.1 d (1.1). The mean time from Dose 1 to first Grade ≥3 local reactions was not estimable. The mean time from first to last Grade ≥3 local reactions was not estimable (Table 14.3.1-1.5.1-3).

The mean time (SD) from Dose 2 to first local reaction was 1.2 d (0.4), while the mean time (SD) from first to last local reactions was 2.5 d (1.4). The mean time (SD) from Dose 2 to first Grade ≥3 local reaction was not estimable. The mean time (SD) from first to last Grade ≥3 local reaction was not estimable (Table 14.3.1-1.5.1-3).

After Dose 1, except for 1 (17%) for the 3 µg dose group, there were no local reactions after Day 7. After Dose 2, except for 1 (17%) for the 3 µg dose group, there were no local reactions after Day 4. For the 3 µg dose group, there was at least 1 (10%) local reaction on each day thereafter up to Day 7.

The participant's diary compliance for reporting local reactions after Dose 1 was 100% up to Day 6 before dropping on Day 7 in some dose groups, while after Dose 2 it was ≥95% up to Day 7 (Table 14.3.2-1.2-3, Listing 16.2.3-1.2-3).

12.3.6.2 Older participants and all (younger and older) participants

The mean time (SD) from Dose 1 to first local reaction was 1.3 d (0.5), while the mean time (SD) from first local reaction to last local reaction was 2.0 d (1.3). The mean time from Dose 1 to first Grade ≥3 local reaction was not estimable. The mean time from first to last Grade ≥3 local reaction was not estimable (Table 14.3.1-1.5.1-3).

The mean time (SD) from Dose 2 to first local reaction was 1.2 d (0.4), while the mean time (SD) from first to last local reactions was 2.6 d (1.6). The mean time (SD) from Dose 2 to first Grade ≥3 local reaction was 2.0 d (not estimable [NE]). The mean time (SD) from first to last Grade ≥3 local reaction was 1.0 d (NE) (Table 14.3.1-1.5.1-3).

After Dose 1, except for 1 (14%) for the 10 µg dose group, there were no local reactions after Day 4. For the 3 µg dose group, there was at least 1 (14%) local reaction on each day thereafter up to Day 7. After Dose 2, except for 2 (29%) for the 3 µg dose group, there were no local reactions after Day 4. For the 3 µg dose group, there was at least 12 (29%) local reactions on each day thereafter up to Day 7.

After Dose 1 and Dose 2, for almost all participants, except for 4 (5%) and 12 participants (18%) respectively, the local reactions resolved within 2 d (Table 14.3.1-1.6.1-3).

The participant's diary compliance for reporting local reactions after Dose 1 was 100% up to Day 5 before dropping on Days 6 and 7 in some dose groups, while after Dose 2 it was ≥96% on Day 5 before dropping on Days 6 and 7 in some dose groups (Table 14.3.2-1.2-3, Listing 16.2.3-1.2-3).

Descriptive statistics of time of solicited local and any solicited reactions by term is presented in Table 14.3.1-1.5.2-3. A summary of solicited local reactions reported by participants (who completed doses 1 and 2) within 7 d after each dose is presented in Table 14.3.1-1.2-3. An overview of solicited local reactions by severity reported by participants (who completed doses 1 and 2) within 7 d after each dose is presented in Table 14.3.1-1.4-3.

12.4 Solicited systemic reactions

12.4.1 Solicited systemic reactions within 7 d after each BNT162b1 dose

A summary of solicited systemic reactions is presented in Table 23. All solicited systemic reaction data by participant is given in Listing 16.2.3-1.3-1.

12.4.1.1 Younger participants

Within 7 d days after Dose 1;

- Approximately 85% of participants reported at least one systemic reaction of any grade on at least one occasion.
- In total 19 participants reported Grade ≥3 systemic reactions.
- A possible dose dependency for Grade ≥3 systemic reactions between the 10 µg group (1 participant) and the 20 µg, 30 µg, 50 µg, and 60 µg groups (2, 3, 5, and 8 participants, respectively) was seen.

Within 7 d after Dose 2;

- Approximately 80% of participants reported at least one systemic reaction of any grade on at least one occasion.
- In total 25 participants reported Grade ≥3 systemic reactions.
- No dose dependency for Grade ≥3 systemic reactions as the 10 µg and 20 µg groups have 5 participants each, the 30 µg groups 6 participants) and the 50 µg group has 5 participants. The Dose 2 in the 60 µg group was omitted due to the SRC decision.

Across the 2 intervals combined 77 participants (92%) reported any systemic reaction at any dose, of which 37 (44%) participants reported Grade ≥3 with a possible dose dependency between 10 µg (6 participants), 20 µg (5 participants), 30 µg (6 participants), and 50 µg (8 participants) and 60 µg (8 participants) dose groups.

12.4.1.2 Older participants and all (younger and older) participants

Within 7 d days after Dose 1;

- Approximately 86% of participants reported at least one systemic reaction of any grade on at least one occasion.
- In total 4 participants reported Grade ≥3 systemic reactions.
- No dose dependency for Grade ≥3 systemic reactions between the 10 µg and 20 µg group (1 participant each) and the 30 µg group (2 participants) was seen.

Within 7 d after Dose 2;

- Approximately 86% of participants reported at least one systemic reaction of any grade on at least one occasion.
- In total 8 participants reported Grade ≥3 systemic reactions.
- No dose dependency for Grade ≥3 systemic reactions was seen.

Across the two intervals combined 33 participants (92%) reported any systemic reaction at any dose, of which 10 (28%) participants reported Grade ≥3 with a possible dose dependency between 10 µg and 20 µg (2 and 3 participants) and 30 µg (5 participants), dose groups.

Table 23: Summary of solicited systemic reactions – BNT162b1 (SAF)

Time interval		Younger participants							
		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Dose 1 up to Day 7 after Dose 1	nn	12	12	12	12	12	12	12	84
	Any systemic reaction n (%)	9 (75)	8 (67)	8 (67)	11 (92)	11 (92)	12 (100)	12 (100)	71 (85)
	Any grade >= 3 systemic reaction n (%)	0 (0)	0 (0)	1 (8)	2 (17)	3 (25)	5 (42)	8 (67)	19 (23)
Dose 2 up to Day 7 after Dose 2	nn	12	12	11	11	12	11	N/A	69
	Any systemic reaction n (%)	7 (58)	7 (58)	9 (82)	10 (91)	11 (92)	11 (100)	N/A	55 (80)
	Any grade >= 3 systemic reaction n (%)	3 (25)	1 (8)	5 (45)	5 (45)	6 (50)	5 (45)	N/A	25 (36)
Combined interval	nn	12	12	12	12	12	12	12	84
	Any systemic reaction n (%)	11 (92)	9 (75)	10 (83)	11 (92)	12 (100)	12 (100)	12 (100)	77 (92)
	Any grade >= 3 systemic reaction n (%)	3 (25)	1 (8)	6 (50)	5 (42)	6 (50)	8 (67)	8 (67)	37 (44)

Time interval		Older participants				All Total (N=120)
		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	
Dose 1 up to Day 7 after Dose 1	nn	12	12	12	36	120
	Any systemic reaction n (%)	9 (75)	11 (92)	11 (92)	31 (86)	102 (85)
	Any grade >= 3 systemic reaction n (%)	1 (8)	1 (8)	2 (17)	4 (11)	23 (19)
Dose 2 up to Day 7 after Dose 2	nn	12	11	12	35	104
	Any systemic reaction n (%)	8 (67)	10 (91)	12 (100)	30 (86)	85 (82)
	Any grade >= 3 systemic reaction n (%)	2 (17)	2 (18)	4 (33)	8 (23)	33 (32)
Combined interval	nn	12	12	12	36	120
	Any systemic reaction n (%)	9 (75)	12 (100)	12 (100)	33 (92)	110 (92)
	Any grade >= 3 systemic reaction n (%)	2 (17)	3 (25)	5 (42)	10 (28)	47 (39)

The combined interval is the union of the intervals 'Dose 1 up to Day 7 after Dose 1' and 'Dose 2 up to Day 7 after Dose 2'. The denominator for the percentage calculation is nn.

All = all is the sum of younger and older participants; N = number of participants in the analysis set; n = number of participants with the respective systemic reactions; nn = number of participants with any information on systemic reactions available; N/A = not available; SAF = Safety Set.

Source: Table 14.3.1-2.1-1.

12.4.2 Solicited systemic reactions by severity – BNT162b1

A summary of participants with solicited systemic reactions by severity is given in Table 24 (younger participants) and Table 25 (older participants). The frequency of participants with solicited systemic reactions by term per day is presented in Table 14.3.1-2.6.2-1.

12.4.2.1 Younger participants

Overall, in the combined time interval, after both doses, the majority of the participants experienced mild (n=76, 90%) followed by moderate (n=62, 74%) solicited systemic reactions. A few participants experienced severe (n=37, 44%) solicited systemic reactions.

- The most frequent severe systemic reactions were reported in 50 µg and 60 µg groups (8 participants each [67%]) followed by 10 µg and 30 µg (6 participants each [50%]) groups.
- The most frequently reported solicited systemic reactions of any severity were fatigue (n=68, 81%), headache (n=66, 79%), myalgia (n=51, 61%), malaise (n=50, 60%), and chills (n=47, 56%). The remaining symptom terms were less frequent.
- For nausea, vomiting, diarrhoea, myalgia, arthralgia and fever each symptom was assessed as severe in ≤10% of participants.
- A possible dose dependency for both severe headache and chills was seen with 2 participants at 10 µg vs. 6 participants at 50 µg and 3 participants at 10 µg vs. 5 participants at 50 µg, respectively. A possible dose dependency for both severe fatigue and loss of appetite was seen with each 1 participant at 10 µg vs. 4 participants at 50 µg, respectively.
- No clear pattern of dose dependency was seen across the symptom terms for mild or moderate reactions, with the exception of moderate intensity malaise which was reported for 17% of participants at 10 µg vs. 75% of participants at 50 µg.

12.4.2.2 Older participants and all (younger and older) participants

Overall, in the combined time interval, after both doses, the majority of the participants experienced mild (n=32, 89%) followed by moderate (n=22, 61%) solicited systemic reactions. A few participants experienced severe (n=10, 28%) solicited systemic reactions.

- The most frequent severe systemic reactions were reported in the 30 µg group (5 participants, 42%) followed by 20 µg (3 participants, 25%) and 10 µg (2 participants, 17%) groups.
- The most frequently reported solicited systemic reactions of any severity were headache (n=29, 81%), fatigue (n=27, 75%), myalgia (n=18, 50%), and malaise (n=18, 50%). The remaining symptom terms were less frequent.
- No clear pattern of dose dependency was seen across the symptom terms for mild, moderate, or severe reactions.

Table 24: Frequency of participants with solicited systemic reactions by grade – BNT162b1 (Combined interval) younger participants (SAF)

		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
	nn	12	12	12	12	12	12	12	84
Any	Any n (%)	11 (92)	9 (75)	10 (83)	11 (92)	12 (100)	12 (100)	12 (100)	77 (92)
	Mild n (%)	10 (83)	9 (75)	10 (83)	11 (92)	12 (100)	12 (100)	12 (100)	76 (90)
	Moderate n (%)	7 (58)	8 (67)	7 (58)	9 (75)	10 (83)	12 (100)	9 (75)	62 (74)
	Severe n (%)	3 (25)	1 (8)	6 (50)	5 (42)	6 (50)	8 (67)	8 (67)	37 (44)
Nausea	Any n (%)	2 (17)	1 (8)	4 (33)	5 (42)	4 (33)	5 (42)	4 (33)	25 (30)
	Mild n (%)	2 (17)	1 (8)	3 (25)	5 (42)	2 (17)	5 (42)	3 (25)	21 (25)
	Moderate n (%)	1 (8)	0 (0)	2 (17)	2 (17)	2 (17)	3 (25)	1 (8)	11 (13)
	Severe n (%)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
Vomiting	Any n (%)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	3 (4)
	Mild n (%)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	2 (2)
	Moderate n (%)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	2 (2)
	Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Diarrhea	Any n (%)	1 (8)	1 (8)	2 (17)	1 (8)	1 (8)	2 (17)	1 (8)	9 (11)
	Mild n (%)	1 (8)	1 (8)	2 (17)	1 (8)	1 (8)	2 (17)	1 (8)	9 (11)
	Moderate n (%)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Severe n (%)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	Any n (%)	8 (67)	9 (75)	10 (83)	9 (75)	10 (83)	12 (100)	8 (67)	66 (79)
	Mild n (%)	7 (58)	8 (67)	10 (83)	8 (67)	9 (75)	10 (83)	7 (58)	59 (70)
	Moderate n (%)	5 (42)	5 (42)	4 (33)	8 (67)	9 (75)	8 (67)	3 (25)	42 (50)
	Severe n (%)	0 (0)	0 (0)	2 (17)	4 (33)	5 (42)	6 (50)	3 (25)	20 (24)
Fatigue	Any n (%)	10 (83)	7 (58)	7 (58)	11 (92)	10 (83)	12 (100)	11 (92)	68 (81)
	Mild n (%)	8 (67)	6 (50)	7 (58)	11 (92)	9 (75)	11 (92)	9 (75)	61 (73)
	Moderate n (%)	5 (42)	6 (50)	5 (42)	4 (33)	8 (67)	9 (75)	3 (25)	40 (48)
	Severe n (%)	1 (8)	1 (8)	1 (8)	1 (8)	3 (25)	4 (33)	2 (17)	13 (15)
Myalgia	Any n (%)	5 (42)	2 (17)	7 (58)	7 (58)	10 (83)	9 (75)	11 (92)	51 (61)
	Mild n (%)	3 (25)	2 (17)	7 (58)	7 (58)	7 (58)	7 (58)	10 (83)	43 (51)
	Moderate n (%)	3 (25)	0 (0)	3 (25)	3 (25)	8 (67)	6 (50)	5 (42)	28 (33)
	Severe n (%)	0 (0)	0 (0)	1 (8)	1 (8)	3 (25)	2 (17)	0 (0)	7 (8)
Arthralgia	Any n (%)	2 (17)	1 (8)	4 (33)	3 (25)	8 (67)	6 (50)	5 (42)	29 (35)
	Mild n (%)	2 (17)	0 (0)	3 (25)	3 (25)	6 (50)	5 (42)	4 (33)	23 (27)
	Moderate n (%)	1 (8)	1 (8)	2 (17)	0 (0)	6 (50)	4 (33)	2 (17)	16 (19)
	Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	1 (8)	1 (8)	5 (6)
Chills	Any n (%)	4 (33)	1 (8)	6 (50)	6 (50)	9 (75)	11 (92)	10 (83)	47 (56)
	Mild n (%)	3 (25)	1 (8)	5 (42)	5 (42)	5 (42)	8 (67)	8 (67)	35 (42)
	Moderate n (%)	1 (8)	0 (0)	1 (8)	3 (25)	3 (25)	7 (58)	2 (17)	17 (20)
	Severe n (%)	0 (0)	0 (0)	3 (25)	3 (25)	4 (33)	5 (42)	2 (17)	17 (20)
Loss of Appetite	Any n (%)	2 (17)	1 (8)	7 (58)	5 (42)	6 (50)	10 (83)	6 (50)	37 (44)
	Mild n (%)	1 (8)	1 (8)	6 (50)	5 (42)	4 (33)	8 (67)	5 (42)	30 (36)
	Moderate n (%)	1 (8)	0 (0)	1 (8)	3 (25)	2 (17)	7 (58)	0 (0)	14 (17)
	Severe n (%)	1 (8)	0 (0)	1 (8)	1 (8)	1 (8)	4 (33)	1 (8)	9 (11)

		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Malaise	Any n (%)	2 (17)	2 (17)	7 (58)	8 (67)	10 (83)	12 (100)	9 (75)	50 (60)
	Mild n (%)	2 (17)	2 (17)	7 (58)	8 (67)	9 (75)	12 (100)	8 (67)	48 (57)
	Moderate n (%)	2 (17)	2 (17)	2 (17)	4 (33)	5 (42)	9 (75)	3 (25)	27 (32)
	Severe n (%)	0 (0)	0 (0)	1 (8)	1 (8)	5 (42)	5 (42)	3 (25)	15 (18)
Fever	Any n (%)	1 (8)	1 (8)	4 (33)	4 (33)	5 (42)	7 (58)	4 (33)	26 (31)
	Mild n (%)	0 (0)	0 (0)	3 (25)	0 (0)	4 (33)	5 (42)	3 (25)	15 (18)
	Moderate n (%)	0 (0)	1 (8)	1 (8)	3 (25)	1 (8)	4 (33)	1 (8)	11 (13)
	Severe n (%)	1 (8)	0 (0)	1 (8)	2 (17)	1 (8)	2 (17)	1 (8)	8 (10)

The combined interval is the union of the intervals 'Dose 1 up to Day 7 after Dose 1' and 'Dose 2 up to Day 7 after Dose 2'. The denominator for the percentage calculation is nn.

All = all is the sum of younger and older participants; N = number of participants in the analysis set; n = number of participants with the respective systemic reaction; nn = number of participants with any information on systemic reactions available; SAF = Safety Set.

Source: modified from Table 14.3.1-2.3-1.

Table 25: Frequency of participants with solicited systemic reactions by grade – BNT162b1 (Combined interval) older participants and all participants (SAF)

		Older participants				
		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	All Total (N=120)
	nn	12	12	12	36	120
Any	Any n (%)	9 (75)	12 (100)	12 (100)	33 (92)	110 (92)
	Mild n (%)	8 (67)	12 (100)	12 (100)	32 (89)	108 (90)
	Moderate n (%)	6 (50)	9 (75)	7 (58)	22 (61)	84 (70)
	Severe n (%)	2 (17)	3 (25)	5 (42)	10 (28)	47 (39)
Nausea	Any n (%)	2 (17)	2 (17)	4 (33)	8 (22)	33 (28)
	Mild n (%)	1 (8)	2 (17)	3 (25)	6 (17)	27 (23)
	Moderate n (%)	1 (8)	1 (8)	2 (17)	4 (11)	15 (13)
	Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Vomiting	Any n (%)	2 (17)	0 (0)	1 (8)	3 (8)	6 (5)
	Mild n (%)	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
	Moderate n (%)	1 (8)	0 (0)	1 (8)	2 (6)	4 (3)
	Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Diarrhea	Any n (%)	0 (0)	2 (17)	1 (8)	3 (8)	12 (10)
	Mild n (%)	0 (0)	2 (17)	1 (8)	3 (8)	12 (10)
	Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	Any n (%)	9 (75)	10 (83)	10 (83)	29 (81)	95 (79)
	Mild n (%)	7 (58)	7 (58)	10 (83)	24 (67)	83 (69)
	Moderate n (%)	5 (42)	7 (58)	4 (33)	16 (44)	58 (48)
	Severe n (%)	2 (17)	0 (0)	2 (17)	4 (11)	24 (20)
Fatigue	Any n (%)	7 (58)	8 (67)	12 (100)	27 (75)	95 (79)
	Mild n (%)	5 (42)	8 (67)	11 (92)	24 (67)	85 (71)
	Moderate n (%)	1 (8)	1 (8)	5 (42)	7 (19)	47 (39)
	Severe n (%)	1 (8)	1 (8)	3 (25)	5 (14)	18 (15)

		Older participants				
		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	All Total (N=120)
Myalgia	Any n (%)	4 (33)	6 (50)	8 (67)	18 (50)	69 (58)
	Mild n (%)	4 (33)	5 (42)	8 (67)	17 (47)	60 (50)
	Moderate n (%)	2 (17)	4 (33)	3 (25)	9 (25)	37 (31)
	Severe n (%)	0 (0)	1 (8)	1 (8)	2 (6)	9 (8)
Arthralgia	Any n (%)	3 (25)	6 (50)	6 (50)	15 (42)	44 (37)
	Mild n (%)	3 (25)	5 (42)	6 (50)	14 (39)	37 (31)
	Moderate n (%)	1 (8)	3 (25)	1 (8)	5 (14)	21 (18)
	Severe n (%)	0 (0)	1 (8)	1 (8)	2 (6)	7 (6)
Chills	Any n (%)	3 (25)	7 (58)	7 (58)	17 (47)	64 (53)
	Mild n (%)	3 (25)	4 (33)	5 (42)	12 (33)	47 (39)
	Moderate n (%)	1 (8)	4 (33)	4 (33)	9 (25)	26 (22)
	Severe n (%)	1 (8)	1 (8)	1 (8)	3 (8)	20 (17)
Loss of Appetite	Any n (%)	2 (17)	3 (25)	6 (50)	11 (31)	48 (40)
	Mild n (%)	2 (17)	2 (17)	5 (42)	9 (25)	39 (33)
	Moderate n (%)	0 (0)	1 (8)	2 (17)	3 (8)	17 (14)
	Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	9 (8)
Malaise	Any n (%)	5 (42)	6 (50)	7 (58)	18 (50)	68 (57)
	Mild n (%)	5 (42)	6 (50)	7 (58)	18 (50)	66 (55)
	Moderate n (%)	0 (0)	3 (25)	3 (25)	6 (17)	33 (28)
	Severe n (%)	1 (8)	0 (0)	1 (8)	2 (6)	17 (14)

The combined interval is the union of the intervals 'Dose 1 up to Day 7 after Dose 1' and 'Dose 2 up to Day 7 after Dose 2'. The denominator for the percentage calculation is nn.

All = all is the sum of younger and older participants; N = number of participants in the analysis set; n = number of participants with the respective systemic reaction; nn = number of participants with any information on systemic reactions available; SAF = Safety Set.

Source: modified from Table 14.3.1-2.3-1.

12.4.3 Time to onset and duration of systemic reactions – BNT162b1

12.4.3.1 Younger participants

The mean time (SD) from Dose 1 to first systemic reaction was 1.2 d (0.8), while the mean time (SD) from first to last systemic reaction was 3.2 d (2.2). The mean time (SD) from Dose 1 to first Grade ≥3 systemic reaction was 1.4 d (0.5). The mean time (SD) from first to last Grade ≥3 systemic reaction was 1.2 d (0.4) (Table 14.3.1-2.5.1-1).

The mean time (SD) from Dose 2 to first systemic reaction was 1.1 d (0.4), while the mean time (SD) from first to last systemic reaction was 3.5 d (1.9). The mean time (SD) from Dose 2 to first Grade ≥3 systemic reaction was 1.3 d (0.6). The mean time (SD) from first to last Grade ≥3 systemic reaction was 1.4 d (0.6) (Table 14.3.1-2.5.1-1).

After Dose 1, except for 1 (13%) for the 3 µg and 10 µg dose groups, there were no systemic reactions on Day 7. After Dose 2, except for 2 (22%) for the 10 µg dose group, there were no systemic reactions on Day 7 (Table 14.3.1-2.6.1-1).

The participant's diary compliance for reporting systemic reactions after Dose 1 was 100% up to Day 6 before dropping on Day 7 in some dose groups, while after Dose 2 it was

≥92% up to Day 5 before dropping on Days 6 and 7 in some dose groups (Table 14.3.2-1.3-1, Listing 16.2.3-1.4-1).

12.4.3.2 Older participants and all (younger and older) participants

The mean time (SD) from Dose 1 to first systemic reaction was 1.5 d (0.6), while the mean time (SD) from first to last systemic reaction was 2.6 d (1.8). The mean time (SD) from Dose 1 to first Grade ≥3 systemic reaction was 1.5 d (0.6). The mean time (SD) from first to last Grade ≥3 systemic reaction was 1.0 d (0.0) (Table 14.3.1-2.5.1-1).

The mean time (SD) from Dose 2 to first systemic reaction was 1.2 d (0.4), while the mean time (SD) from first to last systemic reaction was 3.0 d (1.7). The mean time (SD) from Dose 2 to first Grade ≥3 systemic reaction was 1.3 d (0.5). The mean time (SD) from first to last Grade ≥3 systemic reaction was 1.4 d (0.5) (Table 14.3.1-2.5.1-1).

After Dose 1 there were no systemic reactions on Day 7. After Dose 2, except for 1 (10%) for the 20 µg dose group, there were no systemic reactions on Day 7 (Table 14.3.1-2.6.1-1).

The participant's diary compliance for reporting systemic reactions after Dose 1 was 100% up to Day 6 before dropping on Day 7 in some dose groups, while after Dose 2 it was ≥92% up to Day 5 before dropping on Days 6 and 7 in some dose groups (Table 14.3.2-1.3-1, Listing 16.2.3-1.4-1).

Descriptive statistics of time of solicited systemic reactions by term is presented in Table 14.3.1-2.5.2-1. A summary of solicited systemic reactions reported by participants (who completed doses 1 and 2) within 7 d after each dose is presented in Table 14.3.1-2.2-1. An overview of solicited systemic reactions by severity experienced by participants who completed both the doses is presented in Table 14.3.1-2.4-1.

12.4.4 Solicited systemic reactions within 7 d after each BNT162b2 dose

A summary of solicited systemic reactions is presented in Table 26. All solicited systemic reaction data by participant is given in Listing 16.2.3-1.3-3.

12.4.4.1 Younger participants

Within 7 d after Dose 1;

- Approximately 80% of participants reported at least one systemic reaction of any grade on at least one occasion.
- There was only 1 participant in the 20 µg group for whom a Grade ≥3 systemic reaction was reported.
- No dose dependency was apparent for any or high-grade systemic reactions.

Within 7 d after Dose 2;

- Approximately 57% of participants reported at least one systemic reaction of any grade on at least one occasion.
- Five participants reported a Grade ≥3 systemic reaction.

- A dose dependency was seen across all grades of systemic reactions.
- A possible dose dependency for Grade ≥3 systemic reactions between the 10 µg group (1 participant) and 30 µg group (3 participants) was seen.
- Across the 2 intervals combined 88% of participants reported any systemic reaction at any dose, of which 6 participants reported Grade ≥3 with a possible dose dependency between 10 µg and higher doses.
- The 30 µg dose (selected for ongoing development) demonstrated similar tolerability to the 20 µg dose.

12.4.4.2 Older participants and all (younger and older) participants

Within 7 d after Dose 1;

- Approximately 44% of participants reported at least one systemic reaction of any grade on at least one occasion.
- There was only 1 participant in the 10 µg group for whom a Grade ≥3 systemic reaction was reported.
- No dose dependency was apparent for any or high-grade systemic reactions.

Within 7 d after Dose 2;

- Approximately 64% of participants reported at least one systemic reaction of any grade on at least one occasion.
- Three participants reported a Grade ≥3 systemic reaction.
- A dose dependency was seen across all grades of systemic reactions.
- A possible dose dependency for Grade ≥3 systemic reactions between the 10 µg group (1 participant) and 30 µg group (2 participants) was seen.
- Across the 2 intervals combined 72% of participants reported any systemic reaction at any dose, of which 4 participants reported Grade ≥3 with no dose dependency between 10 µg and higher doses.
- The 30 µg dose (selected for ongoing development) demonstrated similar tolerability to the 20 µg dose.

Table 26: Summary of solicited systemic reactions – BNT162b2 (SAF)

Time interval		Younger participants					
		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Dose 1 up to Day 7 after Dose 1	nn	12	12	12	12	12	60
	Any systemic reaction n (%)	9 (75)	9 (75)	12 (100)	9 (75)	9 (75)	48 (80)
	Any grade >= 3 systemic reaction n (%)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Dose 2 up to Day 7 after Dose 2	nn	11	12	11	12	12	58
	Any systemic reaction n (%)	4 (36)	2 (17)	7 (64)	10 (83)	10 (83)	33 (57)
	Any grade >= 3 systemic reaction n (%)	0 (0)	0 (0)	1 (9)	1 (8)	3 (25)	5 (9)
Combined interval	nn	12	12	12	12	12	60
	Any systemic reaction n (%)	9 (75)	9 (75)	12 (100)	11 (92)	12 (100)	53 (88)
	Any grade >= 3 systemic reaction n (%)	0 (0)	0 (0)	1 (8)	2 (17)	3 (25)	6 (10)

Time interval		Older participants				All Total (N=96)
		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	
Dose 1 up to Day 7 after Dose 1	nn	12	12	12	36	96
	Any systemic reaction n (%)	3 (25)	4 (33)	9 (75)	16 (44)	64 (67)
	Any grade >= 3 systemic reaction n (%)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Dose 2 up to Day 7 after Dose 2	nn	12	12	12	36	94
	Any systemic reaction n (%)	4 (33)	8 (67)	11 (92)	23 (64)	56 (60)
	Any grade >= 3 systemic reaction n (%)	1 (8)	0 (0)	2 (17)	3 (8)	8 (9)
Combined interval	nn	12	12	12	36	96
	Any systemic reaction n (%)	5 (42)	10 (83)	11 (92)	26 (72)	79 (82)
	Any grade >= 3 systemic reaction n (%)	2 (17)	0 (0)	2 (17)	4 (11)	10 (10)

The combined interval is the union of the intervals Dose 1 up to Day 7 after Dose 1 and Dose 2 up to Day 7 after Dose 2.

The denominator for the percentage calculation is nn.

All = all is the sum of younger and older participants; N = number of participants in the analysis set; n = number of participants with the respective systemic reactions; nn = number of participants with any information on systemic reactions available; SAF = Safety Set.

Source: Table 14.3.1-2.1-3.

12.4.5 Solicited systemic reactions by severity – BNT162b2

An overview of solicited systemic reactions by severity is presented in Table 27. The frequency of participants with solicited systemic reactions by term per day is presented in Table 14.3.1-2.6.2-3.

12.4.5.1 Younger participants

Overall, in the combined time interval after both doses, the majority of the younger participants experienced mild (n=53, 88%) followed by moderate (n=23, 38%) solicited systemic reactions. A few participants experienced severe (n=6, 10%) solicited systemic reactions.

- Severe grade systemic reactions were reported in 30 µg (3 participants [25%]), 20 µg (2 participants [17%]), and 10 µg (1 participant [8%]) dose groups.
- The most frequently reported solicited systemic reactions of any severity were fatigue (n=40, 67%), followed by headache (n=32, 53%), malaise (n=24, 40%), and myalgia (n=23, 38%). The remaining symptom terms were less frequent.
- Most symptom terms reported were predominantly at mild intensity with a ratio of mild to moderate reports of between 3:1 and 2:1.
- Only mild reactions were reported for diarrhoea and fever.
- For nausea, headache, fatigue, myalgia, chills, arthralgia and malaise each symptom was assessed as severe in <10% of participants.
- A possible dose dependency for both severe fatigue and arthralgia was seen with 0 participants at 10 µg vs. 2 participants at 30 µg, and 0 participants at 10 µg vs. 3 participants at 30 µg, respectively.
- Similarly, no clear pattern of dose dependency was seen across the symptom terms for mild reactions or moderate reactions, with the exception of moderate intensity malaise which was reported for 1 participant receiving 10 µg and 6 participants with 30 µg dose.
- For the 30 µg dose selected for further development, there were consistently slightly higher rates of reporting systemic reactions than for the next lowest 20 µg level for every individual symptom term except headache, diarrhoea, fatigue, and fever. The difference is pronounced for malaise 33% (20 µg) vs. 58% (30 µg) and arthralgia 17% (20 µg) vs. 50% (30 µg).
- No major differences were noted between the pattern seen for the combined time intervals and the individual reporting period.

12.4.5.2 Older participants and all (younger and older) participants

Overall, in the combined time interval after both doses, the majority of the older participants experienced mild (n=25, 69%) followed by moderate (n=13, 36%) solicited systemic reactions. A few participants experienced severe (n=4, 11%) solicited systemic reactions.

- Severe grade systemic reactions were reported in 30 µg (2 participants [17%]) and 10 µg (2 participants [17%]) dose groups.
- The most frequently reported solicited systemic reactions of any severity were fatigue (n=20, 56%), followed by headache (n=17, 47%), malaise (n=12, 33%), and myalgia (n=12, 33%). The remaining symptom terms were less frequent.

- Most symptom terms reported were predominantly at mild intensity with a ratio of mild to moderate reports of between 3:1 and 2:1.
- Only mild reactions were reported for diarrhoea and fever.
- All symptoms were assessed as severe in <10% of participants.
- For the 30 µg dose selected for further development, there were consistently slightly higher rates of reporting systemic reactions than for the next lowest 20 µg level for every individual symptom term. The difference is pronounced for moderate malaise 8% (20 µg) vs. 50% (30 µg).
- No major differences were noted between the pattern seen for the combined time intervals and the individual reporting period.

Table 27: Frequency of participants with solicited systemic reactions by grade for – BNT162b2 (Combined interval) younger participants (SAF)

Note: lines with only zero values are not shown		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
	nn	12	12	12	12	12	60
Any	Any n (%)	9 (75)	9 (75)	12 (100)	11 (92)	12 (100)	53 (88)
	Mild n (%)	9 (75)	9 (75)	12 (100)	11 (92)	12 (100)	53 (88)
	Moderate n (%)	2 (17)	3 (25)	5 (42)	6 (50)	7 (58)	23 (38)
	Severe n (%)	0 (0)	0 (0)	1 (8)	2 (17)	3 (25)	6 (10)
Nausea	Any n (%)	1 (8)	1 (8)	5 (42)	1 (8)	2 (17)	10 (17)
	Mild n (%)	1 (8)	1 (8)	5 (42)	1 (8)	2 (17)	10 (17)
	Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Diarrhea	Any n (%)	2 (17)	2 (17)	1 (8)	2 (17)	2 (17)	9 (15)
	Mild n (%)	2 (17)	2 (17)	1 (8)	2 (17)	2 (17)	9 (15)
Headache	Any n (%)	3 (25)	6 (50)	9 (75)	7 (58)	7 (58)	32 (53)
	Mild n (%)	3 (25)	5 (42)	7 (58)	7 (58)	6 (50)	28 (47)
	Moderate n (%)	0 (0)	3 (25)	4 (33)	3 (25)	2 (17)	12 (20)
	Severe n (%)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Fatigue	Any n (%)	7 (58)	7 (58)	8 (67)	9 (75)	9 (75)	40 (67)
	Mild n (%)	7 (58)	7 (58)	6 (50)	9 (75)	8 (67)	37 (62)
	Moderate n (%)	1 (8)	0 (0)	3 (25)	3 (25)	4 (33)	11 (18)
	Severe n (%)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	3 (5)
Myalgia	Any n (%)	2 (17)	3 (25)	5 (42)	6 (50)	7 (58)	23 (38)
	Mild n (%)	2 (17)	3 (25)	4 (33)	4 (33)	6 (50)	19 (32)
	Moderate n (%)	1 (8)	0 (0)	0 (0)	3 (25)	2 (17)	6 (10)
	Severe n (%)	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	3 (5)
Arthralgia	Any n (%)	1 (8)	1 (8)	6 (50)	2 (17)	6 (50)	16 (27)
	Mild n (%)	1 (8)	1 (8)	4 (33)	1 (8)	5 (42)	12 (20)
	Moderate n (%)	1 (8)	0 (0)	2 (17)	2 (17)	1 (8)	6 (10)
	Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	3 (5)
Chills	Any n (%)	1 (8)	0 (0)	3 (25)	4 (33)	6 (50)	14 (23)
	Mild n (%)	1 (8)	0 (0)	1 (8)	2 (17)	5 (42)	9 (15)
	Moderate n (%)	0 (0)	0 (0)	2 (17)	1 (8)	1 (8)	4 (7)
	Severe n (%)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)
Loss of Appetite	Any n (%)	1 (8)	1 (8)	1 (8)	1 (8)	2 (17)	6 (10)
	Mild n (%)	1 (8)	1 (8)	1 (8)	1 (8)	1 (8)	5 (8)
	Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Malaise	Any n (%)	4 (33)	5 (42)	4 (33)	4 (33)	7 (58)	24 (40)
	Mild n (%)	4 (33)	5 (42)	2 (17)	3 (25)	5 (42)	19 (32)
	Moderate n (%)	1 (8)	0 (0)	1 (8)	1 (8)	6 (50)	9 (15)
	Severe n (%)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
Fever	Any n (%)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (3)
	Mild n (%)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (3)

The combined interval is the union of the intervals 'Dose 1 up to Day 7 after Dose 1' and 'Dose 2 up to Day 7 after Dose 2'. The denominator for the percentage calculation is nn.

N = number of participants in the analysis set; n = number of participants with the respective systemic reaction; nn = number of participants with any information on systemic reactions available; - = not estimable; SAF = Safety Set.

Source: modified from Table 14.3.1-2.3-3.

Table 28: Frequency of participants with solicited systemic reactions by grade for – BNT162b2 (combined interval) older participants and all participants (SAF)

Note: lines with only zero values are not shown		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	All Total (N=96)
	nn	12	12	12	36	96
Any	Any n (%)	5 (42)	10 (83)	11 (92)	26 (72)	79 (82)
	Mild n (%)	4 (33)	10 (83)	11 (92)	25 (69)	78 (81)
	Moderate n (%)	3 (25)	3 (25)	7 (58)	13 (36)	36 (38)
	Severe n (%)	2 (17)	0 (0)	2 (17)	4 (11)	10 (10)
Nausea	Any n (%)	3 (25)	0 (0)	3 (25)	6 (17)	16 (17)
	Mild n (%)	2 (17)	0 (0)	3 (25)	5 (14)	15 (16)
	Severe n (%)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Diarrhea	Any n (%)	1 (8)	0 (0)	2 (17)	3 (8)	12 (13)
	Mild n (%)	1 (8)	0 (0)	2 (17)	3 (8)	12 (13)
Headache	Any n (%)	3 (25)	6 (50)	8 (67)	17 (47)	49 (51)
	Mild n (%)	2 (17)	6 (50)	7 (58)	15 (42)	43 (45)
	Moderate n (%)	2 (17)	2 (17)	3 (25)	7 (19)	19 (20)
	Severe n (%)	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Fatigue	Any n (%)	4 (33)	7 (58)	9 (75)	20 (56)	60 (63)
	Mild n (%)	3 (25)	7 (58)	8 (67)	18 (50)	55 (57)
	Moderate n (%)	3 (25)	2 (17)	3 (25)	8 (22)	19 (20)
	Severe n (%)	1 (8)	0 (0)	0 (0)	1 (3)	4 (4)
Myalgia	Any n (%)	3 (25)	4 (33)	5 (42)	12 (33)	35 (36)
	Mild n (%)	1 (8)	4 (33)	5 (42)	10 (28)	29 (30)
	Moderate n (%)	2 (17)	1 (8)	1 (8)	4 (11)	10 (10)
	Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Arthralgia	Any n (%)	1 (8)	1 (8)	3 (25)	5 (14)	21 (22)
	Mild n (%)	1 (8)	1 (8)	3 (25)	5 (14)	17 (18)
	Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
	Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Chills	Any n (%)	0 (0)	1 (8)	4 (33)	5 (14)	19 (20)
	Mild n (%)	0 (0)	1 (8)	3 (25)	4 (11)	13 (14)
	Moderate n (%)	0 (0)	0 (0)	2 (17)	2 (6)	6 (6)
	Severe n (%)	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Loss of Appetite	Any n (%)	2 (17)	1 (8)	3 (25)	6 (17)	12 (13)
	Mild n (%)	1 (8)	1 (8)	3 (25)	5 (14)	10 (10)
	Moderate n (%)	1 (8)	0 (0)	1 (8)	2 (6)	3 (3)
Malaise	Any n (%)	3 (25)	2 (17)	7 (58)	12 (33)	36 (38)
	Mild n (%)	2 (17)	2 (17)	5 (42)	9 (25)	28 (29)
	Moderate n (%)	1 (8)	0 (0)	3 (25)	4 (11)	13 (14)
	Severe n (%)	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
Fever	Any n (%)	0 (0)	0 (0)	3 (25)	3 (8)	5 (5)
	Mild n (%)	0 (0)	0 (0)	3 (25)	3 (8)	5 (5)

The combined interval is the union of the intervals 'Dose 1 up to Day 7 after Dose 1' and 'Dose 2 up to Day 7 after Dose 2'. The denominator for the percentage calculation is nn.

All = all is the sum of younger and older participants; N = number of participants in the analysis set; n = number of participants with the respective systemic reaction; nn = number of participants with any information on systemic reactions available; SAF Safety Set.

Source: modified from Table 14.3.1-2.3-3.

12.4.6 Time to onset and duration of systemic reactions – BNT162b2

12.4.6.1 Younger participants

The mean time (SD) from Dose 1 to first systemic reaction was 1.8 d (1.6), while the mean time (SD) from first to last systemic reaction was 2.6 d (2.1). The mean time (SD) from Dose 1 to first Grade ≥3 systemic reaction was 2.0 d (NE). The mean time (SD) from first to last Grade ≥3 systemic reaction was 1.0 d (NE) (Table 14.3.1-2.5.1-3).

The mean time (SD) from Dose 2 to first systemic reaction was 1.3 d (0.5), while the mean time (SD) from first to last systemic reaction was 2.7 d (2.2). The mean time (SD) from Dose 2 to first Grade ≥3 systemic reaction was 2.2 d (1.1). The mean time (SD) from first to last Grade ≥3 systemic reaction was 1.2 d (0.4) (Table 14.3.1-2.5.1-3).

After Dose 1 and Dose 2, for almost all participants, except for 2 (4%) and 2 participants (6%) respectively, the systemic reactions resolved within 7 d (Table 14.3.1-2.6.1-3).

The participant's diary compliance for reporting systemic reactions after Dose 1 was 100% up to Day 6 before dropping in some dose groups on Day 7, while after Dose 2 it was 100% in all but one dose group (1 µg) up to Day 6 before dropping in some dose groups on Day 7 (Table 14.3.2-1.3-3, Listing 16.2.3-1.4-3).

12.4.6.2 Older participants and all (younger and older) participants

The mean time (SD) from Dose 1 to first systemic reaction was 1.6 d (0.9), while the mean time (SD) from first to last systemic reaction was 2.9 d (2.4). The mean time (SD) from Dose 1 to first Grade ≥3 systemic reaction was 1.0 d (NE). The mean time (SD) from first to last Grade ≥3 systemic reaction was 1.0 d (NE) (Table 14.3.1-2.5.1-3).

The mean time (SD) from Dose 2 to first systemic reaction was 1.5 d (1.3), while the mean time (SD) from first to last systemic reaction was 2.2 d (1.5). The mean time (SD) from Dose 2 to first Grade ≥3 systemic reaction was 1.3 d (0.6). The mean time (SD) from first to last Grade ≥3 systemic reaction was 1.3 d (0.6) (Table 14.3.1-2.5.1-3).

After Dose 1 and Dose 2, for almost all participants, except for 2 (3%) and 2 participants (4%) respectively, the systemic reactions resolved within 7 d (Table 14.3.1-2.6.1-3).

The participant's diary compliance for reporting systemic reactions after Dose 1 was 100% up to Day 6 before dropping in some dose groups on Day 7, while after Dose 2 it was 100% up to Day 5 before dropping in some dose groups on Days 6 and 7 (Table 14.3.2-1.3-3, Listing 16.2.3-1.4-3).

Descriptive statistics of time of solicited systemic reactions by term is presented in Table 14.3.1-2.5.2-3. A summary of solicited systemic reactions reported by participants (who completed doses 1 and 2) within 7 d after each dose is presented in Table 14.3.1-2.2-3. A summary of participants (who completed doses 1 and 2) with solicited systemic reactions by severity is given in Table 14.3.1-2.4-3.

12.5 Adverse events

12.5.1 Overview of adverse events

12.5.1.1 Unsolicited TEAEs after BNT162b1 dosing

A summary of unsolicited TEAEs without AEs based on solicited reporting via diaries is presented in Table 29 (Safety Set) and Table 30 (SAFB) for the younger participants and in Table 31 (Safety Set) and Table 32 (SAFB) for the older participants. All unsolicited TEAEs data by participant is given in Listing 16.2.3-1.6-1.

12.5.1.1.1 Younger participants

Within 7 d after Dose 1, 16 participants (19%) experienced in total 24 TEAEs of which 23 events were related TEAEs, except for one TEAE reported in 1 µg dose group (Table 29).

- Six participants (50%) in 60 µg reported in total 8 TEAEs, 3 participants (25%) in 10 µg reported in total 7 TEAEs, 3 participants (25%) in 20 µg reported in total 4 TEAEs, 2 participants (17%) in 30 µg reported in total 2 TEAEs, 1 participant (8%) in 50 µg reported in total 1 TEAE.
- None of the participants reported any TEAEs with Grade ≥3 severity.

Within 28 d after Dose 1 or up to Dose 2, 21 participants (25%) experienced in total 39 TEAEs of which, 24 events were related TEAEs (Table 29).

- Six participants (50%) in 60 µg reported in total 9 TEAEs, 4 participants (33%) in 10 µg reported in total 11 TEAEs, 4 participants (33%) in 30 µg reported in total 5 TEAEs, 3 participants each (25%) in 50 µg and 20 µg reported in total 4 TEAEs.
- Of which, 24 events were related TEAEs. Of which, 6 participants (50%) in 60 µg reported in total 8 related TEAEs, 3 participants (25%) in 10 µg reported in total 7 related TEAEs, 3 participants (25%) in 20 µg reported in total 4 related TEAEs, 3 participants (25%) in 30 µg reported in total 3 related TEAEs, 1 participant (8%) in 50 µg reported in total 1 related TEAE.
- None of the participants reported any TEAEs with Grade ≥3 severity.

Within 7 d after Dose 2 in the SAFB, 18 participants (26%) experienced in total 34 TEAEs of which, 27 events were related TEAEs (Table 30).

- Six participants (55%) in 50 µg reported in total 10 TEAEs, 3 participants (27%) in 10 µg reported in total 3 TEAEs, 3 participants (27%) in 20 µg reported in total 8 TEAEs, and 1 participant (8%) in 30 µg reported in total 1 TEAE. The Dose 2 in the 60 µg group was omitted due to the SRC decision, hence the results are unavailable.
- Five participants (45%) in 50 µg reported in total 9 related TEAEs, 3 participants (27%) in 10 µg reported in total 3 related TEAEs, 2 participants (18%) in 20 µg reported in total 5 related TEAEs, 1 participant (8%) in 30 µg dose groups reported in total 1 related TEAE.

- Two participants in the 20 µg group reported 4 TEAEs with Grade ≥3 severity, of which 1 participant (9%) reported in total 3 related Grade ≥3 TEAEs.

Within 28 d after Dose 2 in the SAFB, 22 participants (32%) experienced in total 45 TEAEs of which, 28 events were related TEAEs (Table 30).

- Six participants (55%) in 50 µg reported in total 13 TEAEs, 4 participants (36%) in 10 µg reported in total 5 TEAEs, 3 participants (27%) in 20 µg reported in total 8 TEAEs, and 3 participants (25%) in 30 µg reported in total 4 TEAEs.
- Of which, 5 participants (45%) in 50 µg reported in total 9 related TEAEs, 3 participants (27%) in 10 µg reported in total 3 related TEAEs, 2 participants (17%) in 30 µg dose groups reported in total 2 related TEAEs, and 2 participants (18%) in 20 µg dose groups reported in total 5 related TEAEs.
- Two participants in the 20 µg group reported 4 TEAEs with Grade ≥3 severity, of which 1 participant (9%) reported in total 3 related Grade ≥3 TEAEs.

Within 28 d after Dose 1 or Dose 2, 38 participants (45%) experienced in total 83 TEAEs of which 51 events were related TEAEs (Table 29).

- Eight participants (67%) in 50 µg reported in total 17 TEAEs, 7 participants (58%) in 10 µg reported in total 16 TEAEs, 6 participants (50%) in 60 µg reported in total 9 TEAEs, 6 participants (50%) in 30 µg reported in total 8 TEAEs, and 5 participants (42%) in 20 µg reported in total 12 TEAEs.
- Six participants (50%) in 10 µg reported in total 10 related TEAEs, 6 participants (50%) in 50 µg reported in total 10 related TEAEs, 6 participants (50%) in 60 µg reported in total 8 related TEAEs, 4 participants (33%) in 20 µg reported in total 9 related TEAEs, 4 participants (33%) in 30 µg reported in total 4 related TEAEs.
- Two participants in the 20 µg group reported 4 TEAEs with Grade ≥3 severity.

Table 29: Summary of TEAEs without AEs based on solicited reporting via diaries – BNT162b1 – Younger participants (SAF)

Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	50 µg (N=12) n (%) E	60 µg (N=12) n (%) E	Total (N=84) n (%) E
Dose 1 up to Day 7 after Dose 1	Any TEAE	1 (8) 2	0 (0) 0	3 (25) 7	3 (25) 4	2 (17) 2	1 (8) 1	6 (50) 8	16 (19) 24
	Related TEAE	1 (8) 1	0 (0) 0	3 (25) 7	3 (25) 4	2 (17) 2	1 (8) 1	6 (50) 8	16 (19) 23
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Dose 1 up to Dose 2 or Day 28 after Dose 1 (whatever comes first)	Any TEAE	1 (8) 6	0 (0) 0	4 (33) 11	3 (25) 4	4 (33) 5	3 (25) 4	6 (50) 9	21 (25) 39
	Related TEAE	1 (8) 1	0 (0) 0	3 (25) 7	3 (25) 4	3 (25) 3	1 (8) 1	6 (50) 8	17 (20) 24
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Dose 1 up to Day 28 after Dose 2 or after Dose 1 (if no Dose 2)	Any TEAE	6 (50) 21	0 (0) 0	7 (58) 16	5 (42) 12	6 (50) 8	8 (67) 17	6 (50) 9	38 (45) 83
	Related TEAE	4 (33) 10	0 (0) 0	6 (50) 10	4 (33) 9	4 (33) 4	6 (50) 10	6 (50) 8	30 (36) 51
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	2 (17) 4	0 (0) 0	0 (0) 0	0 (0) 0	2 (2) 4
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	1 (8) 3	0 (0) 0	0 (0) 0	0 (0) 0	1 (1) 3
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.

AE = adverse event; E = number of events; N = number of participants in the analysis set; n = number of participants with the specified characteristic; TEAE = treatment-emergent adverse event; TESAE = treatment-emergent serious adverse event; SAF = Safety Set.

Source: modified from Table 14.3.1-3.1.3-1.

A summary of TEAEs without AEs based on solicited reporting via diaries is given using Safety Dose 2 set (SAFB) (Table 30), because the decision was made not to give the second 60 µg dose (Dose 2).

Table 30: Summary of TEAEs without AEs based on solicited reporting via diaries – BNT162b1 – Younger participants (SAFB)

Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=11) n (%) E	20 µg (N=11) n (%) E	30 µg (N=12) n (%) E	50 µg (N=11) n (%) E	Total (N=69) n (%) E
Dose 2 up to Day 7 after Dose 2	Any TEAE	5 (42) 12	0 (0) 0	3 (27) 3	3 (27) 8	1 (8) 1	6 (55) 10	18 (26) 34
	Related TEAE	4 (33) 9	0 (0) 0	3 (27) 3	2 (18) 5	1 (8) 1	5 (45) 9	15 (22) 27
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	2 (18) 4	0 (0) 0	0 (0) 0	2 (3) 4
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	1 (9) 3	0 (0) 0	0 (0) 0	1 (1) 3
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Dose 2 up to Day 28 after Dose 2	Any TEAE	6 (50) 15	0 (0) 0	4 (36) 5	3 (27) 8	3 (25) 4	6 (55) 13	22 (32) 45
	Related TEAE	4 (33) 9	0 (0) 0	3 (27) 3	2 (18) 5	2 (17) 2	5 (45) 9	16 (23) 28
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	2 (18) 4	0 (0) 0	0 (0) 0	2 (3) 4
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	1 (9) 3	0 (0) 0	0 (0) 0	1 (1) 3
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.

AE = adverse event; E = number of events; N = number of participants in the analysis set; n = number of participants with the specified characteristic; TEAE = treatment-emergent adverse event; TESAE = treatment-emergent serious adverse event; SAFB = Safety Dose 2 Set (Safety Boost Set).

Source: modified from Table 14.3.1-3.1.3-1.

12.5.1.1.2 Older participants and all (younger and older) participants

Within 7 d after Dose 1, 5 participants (14%), all in the 30 µg group, experienced in total 9 TEAEs of which 6 events were related TEAEs (Table 31).

- One participant in the 30 µg group reported a TEAE with Grade ≥3 severity.

Within 28 d after Dose 1 or up to Dose 2, 12 participants (33%) experienced in total 20 TEAEs of which 6 events were related TEAEs.

- Seven participants (58%) in 30 µg reported in total 13 TEAEs, 3 participants (25%) in 10 µg reported in total 3 TEAEs, and 2 participants (17%) in 20 µg reported in total 4 TEAEs.
- One participant in each dose group reported a TEAE with Grade ≥3 severity.

Within 7 d after Dose 2 in the SAFB, 4 participants in the 30 µg group reported 4 TEAEs of which 3 were related events. One participant reported 1 TEAE with Grade ≥3 severity that was also related (Table 32).

Within 28 d after Dose 2 in the SAFB, 4 participants in the 30 µg group reported 4 TEAEs of which 3 were related events. One participant reported 1 TEAE with Grade ≥3 severity that was also related.

Within 28 d after Dose 1 or Dose 2 in the SAF, 13 participants (36%) experienced in total 24 TEAEs of which 9 were related TEAEs.

- Eight participants (67%) in 30 µg reported in total 17 TEAEs, 3 participants (25%) in 10 µg reported in total 3 TEAEs, and 2 participants (17%) in 20 µg reported in total 4 TEAEs.
- Overall, four participants (11%) reported 4 TEAEs with Grade ≥3 severity.

Table 31: Summary of TEAEs without AEs based on solicited reporting via diaries – BNT162b1 older participants and all participants (SAF)

		Dose ranging groups				All
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=120) n (%) E
Dose 1 up to Day 7 after Dose 1	Any TEAE	0 (0) 0	0 (0) 0	5 (42) 9	5 (14) 9	21 (18) 33
	Related TEAE	0 (0) 0	0 (0) 0	4 (33) 6	4 (11) 6	20 (17) 29
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Dose 1 up to Dose 2 or Day 28 after Dose 1 (whatever comes first)	Any TEAE	3 (25) 3	2 (17) 4	7 (58) 13	12 (33) 20	33 (28) 59
	Related TEAE	0 (0) 0	0 (0) 0	4 (33) 6	4 (11) 6	21 (18) 30
	Grade >=3 TEAE	1 (8) 1	1 (8) 1	1 (8) 1	3 (8) 3	3 (3) 3
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Dose 1 up to Day 28 after Dose 2 or after Dose 1 (if no Dose 2)	Any TEAE	3 (25) 3	2 (17) 4	8 (67) 17	13 (36) 24	51 (43) 107
	Related TEAE	0 (0) 0	0 (0) 0	5 (42) 9	5 (14) 9	35 (29) 60
	Grade >=3 TEAE	1 (8) 1	1 (8) 1	2 (17) 2	4 (11) 4	6 (5) 8
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	2 (2) 4
	Any TESAE	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.

All = all is the sum of younger and older participants; AE = adverse event; E = number of events; N = number of participants in the analysis set; n = number of participants with the specified characteristic; TEAE = treatment-emergent adverse event; TESAE = treatment-emergent serious adverse event; SAF = Safety Set.

Source: modified from Table 14.3.1-3.1.3-1.

Table 32: Summary of TEAEs without AEs based on solicited reporting via diaries – BNT162b1 older participants and all participants (SAFB)

Time interval		Older participants				All
		10 µg (N=12) n (%) E	20 µg (N=11) n (%) E	30 µg (N=12) n (%) E	Total (N=35) n (%) E	Total (N=104) n (%) E
Dose 2 up to Day 7 after Dose 2	Any TEAE	0 (0) 0	0 (0) 0	4 (33) 4	4 (11) 4	22 (21) 38
	Related TEAE	0 (0) 0	0 (0) 0	3 (25) 3	3 (9) 3	18 (17) 30
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	3 (3) 5
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	2 (2) 4
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Dose 2 up to Day 28 after Dose 2	Any TEAE	0 (0) 0	0 (0) 0	4 (33) 4	4 (11) 4	26 (25) 49
	Related TEAE	0 (0) 0	0 (0) 0	3 (25) 3	3 (9) 3	19 (18) 31
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	3 (3) 5
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	2 (2) 4
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.

All = all younger and older participants; AE = adverse event; E = number of events; N = number of participants in the analysis set; n = number of participants with the specified characteristic; TEAE = treatment-emergent adverse event; TESAE = treatment-emergent serious adverse event; SAFB = Safety Boost Set.

Source: modified from Table 14.3.1-3.1.3-1.

A summary of TEAEs is presented in Table 14.3.1-3.1.1-1. A summary of TEAEs in the completer set is presented in Table 14.3.1-3.1.2-1. A summary of TEAEs by SOC and PT in the completer set is presented in Table 14.3.1-3.3.1-1.

12.5.1.2 Unsolicited TEAEs after BNT162b2 dosing

A summary of unsolicited TEAEs without AEs based on solicited reporting via diaries in presented in Table 33 (SAF) for younger participants and Table 34 for older participants. All unsolicited TEAEs data by participant is given in Listing 16.2.3-1.6-3.

12.5.1.2.1 Younger participants

Within 7 d after Dose 1, 11 participants (18%) experienced in total 14 TEAEs of which 2 events were related TEAEs in 3 µg group.

- Three participants (25%) in 30 µg reported in total 4 TEAEs, 2 participants (17%) in 10 µg reported in total 2 TEAEs, 1 participant (8%) in 20 µg reported in total 1 TEAE.
- None of the participants reported any TEAEs with Grade ≥3 severity.

Within 28 d after Dose 1 or up to Dose 2, 18 participants (30%) experienced in total 26 TEAEs of which 2 events were related TEAEs in the 3 µg group.

- Five participants (42%) in 10 µg reported in total 7 TEAEs, 4 participants (33%) in 30 µg reported in total 5 TEAEs, 1 participant (8%) in 20 µg reported in total 1 TEAE.

- One participant (8%) reported one Grade ≥3 TEAE in 10 µg group.

Within 7 d after Dose 2, 9 participants (15%) experienced in total 14 TEAEs of which 6 events were related TEAEs.

- Three participants (25%) in 10 µg reported in total 3 TEAEs, 1 participant (8%) in 30 µg reported in total 3 TEAEs, 1 participant (8%) in 20 µg reported in total 2 TEAEs.
- Of which, 6 events were related TEAEs; 1 participant (8%) in 30 µg reported in total 3 TEAEs, 1 participant (8%) in 20 µg reported in total 2 TEAEs, 1 participant (8%) in 10 µg reported in total 1 TEAE.
- None of the participants reported any TEAEs with Grade ≥3 severity.

Within 28 d after Dose 2, 15 participants (25%) experienced in total 25 TEAEs of which 7 events were related TEAEs.

- Four participants (33%) in 10 µg reported in total 4 TEAEs, 1 participant (8%) in 30 µg reported in total 3 TEAEs, 1 participant (8%) in 20 µg reported in total 2 TEAEs.
- Of which, 7 events were related TEAEs; 1 participant (8%) in 30 µg reported in total 3 TEAEs, 1 participant (8%) in 20 µg reported in total 2 TEAEs, 1 participant (8%) in 10 µg reported in total 1 TEAE.
- None of the participants reported any TEAEs with Grade ≥3 severity.

Within 28 d after Dose 1 or Dose 2, 26 participants (43%) experienced in total 51 TEAEs of which, 9 events were related TEAEs.

- Seven participants (58%) in 10 µg reported in total 11 TEAEs, 5 participants (42%) in 30 µg reported in total 8 TEAEs, 2 participants (17%) in 20 µg reported in total 3 TEAEs.
- Of which, 9 events were related TEAEs; 1 participant (8%) in 30 µg reported in total 3 TEAEs, 1 participant (8%) in 20 µg reported in total 2 TEAEs, 1 participant (8%) in 10 µg reported in total 1 TEAE.
- One participant (8%) reported one Grade ≥3 TEAE in 10 µg group.

Table 33: Summary of TEAEs without AEs based on solicited reporting via diaries – BNT162b2 – Younger participants (SAF)

Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=60) n (%) E
Dose 1 up to Day 7 after Dose 1	Any TEAE	1 (8) 2	4 (33) 5	2 (17) 2	1 (8) 1	3 (25) 4	11 (18) 14
	Related TEAE	0 (0) 0	2 (17) 2	0 (0) 0	0 (0) 0	0 (0) 0	2 (3) 2
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Dose 1 up to Dose 2 or Day 28 after Dose 1 (whatever comes first)	Any TEAE	2 (17) 3	6 (50) 10	5 (42) 7	1 (8) 1	4 (33) 5	18 (30) 26
	Related TEAE	0 (0) 0	2 (17) 2	0 (0) 0	0 (0) 0	0 (0) 0	2 (3) 2
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	0 (0) 0	0 (0) 0	1 (2) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Dose 2 up to Day 7 after Dose 2	Any TEAE	2 (17) 2	2 (17) 4	3 (25) 3	1 (8) 2	1 (8) 3	9 (15) 14
	Related TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (8) 2	1 (8) 3	3 (5) 6
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Dose 2 up to Day 28 after Dose 2	Any TEAE	4 (33) 4	5 (42) 12	4 (33) 4	1 (8) 2	1 (8) 3	15 (25) 25
	Related TEAE	1 (8) 1	0 (0) 0	1 (8) 1	1 (8) 2	1 (8) 3	4 (7) 7
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Dose 1 up to Day 28 after Dose 2 or after Dose 1 (if no Dose 2)	Any TEAE	5 (42) 7	7 (58) 22	7 (58) 11	2 (17) 3	5 (42) 8	26 (43) 51
	Related TEAE	1 (8) 1	2 (17) 2	1 (8) 1	1 (8) 2	1 (8) 3	6 (10) 9
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	0 (0) 0	0 (0) 0	1 (2) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.

AE = adverse event; E = number of events; N = number of participants in the analysis set; n = number of participants with the specified characteristic; TEAE = treatment-emergent adverse event; TESAE = treatment-emergent serious adverse event; SAF = Safety Set.

Source: Table 14.3.1-3.1.3-3.

12.5.1.2.2 Older participants and all (younger and older) participants

Within 7 d after Dose 1, 6 participants (17%) experienced in total 9 TEAEs of which 1 event was a related TEAE in the 30 µg group.

- Two participants (17%) in 30 µg reported in total 4 TEAEs, 2 participants (17%) in 20 µg reported in total 3 TEAEs, 2 participants (17%) in 10 µg reported in total 2 TEAEs.
- One participant (8%) in 30 µg reported in total 1 TEAE with Grade ≥3 severity.

Within 28 d after Dose 1 or up to Dose 2, 8 participants (22%) experienced in total 13 TEAEs of which 4 events were related TEAEs.

- Three participants (25%) in 10 µg and 30 µg reported in total 5 TEAEs and 2 participants (17%) in 20 µg reported in total 3 TEAEs.
- Two participants (17%) reported 2 Grade ≥3 TEAEs (of which 1 was related) in 30 µg group.

Within 7 d after Dose 2, 1 participant (8%) in the 30 µg group experienced in total 1 not related TEAE.

Within 28 d after Dose 2, 5 participants (14%) experienced in total 7 not related TEAEs.

- One participant reported a TESAE (ankle fracture).

Within 28 d after Dose 1 or Dose 2, 12 participants (33%) experienced in total 20 TEAEs of which 4 events were related TEAEs.

- Three participants (25%) in 30 µg reported in total 6 TEAEs, 6 participants (50%) in 20 µg reported in total 9 TEAEs and 3 participants (25%) in 10 µg reported in total 5 TEAEs.
- Two participants in the 30 µg group reported 2 Grade ≥3 TEAEs and one participant (8%) in 20 µg group reported one Grade ≥3 TEAE.
- One participant reported a not related TESAE (ankle fracture) in 20 µg group.

Table 34: Summary of TEAEs without AEs based on solicited reporting via diaries – BNT162b2 – Older participants and all participants (SAF)

Time interval		Older participants				All
		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=96) n (%) E
Dose 1 up to Day 7 after Dose 1	Any TEAE	2 (17) 2	2 (17) 3	2 (17) 4	6 (17) 9	17 (18) 23
	Related TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	3 (3) 3
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Dose 1 up to Dose 2 or Day 28 after Dose 1 (whatever comes first)	Any TEAE	3 (25) 5	2 (17) 3	3 (25) 5	8 (22) 13	26 (27) 39
	Related TEAE	1 (8) 3	0 (0) 0	1 (8) 1	2 (6) 4	4 (4) 6
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	2 (17) 2	2 (6) 2	3 (3) 3
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Dose 2 up to Day 7 after Dose 2	Any TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	10 (10) 15
	Related TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	3 (3) 6
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Dose 2 up to Day 28 after Dose 2	Any TEAE	0 (0) 0	4 (33) 6	1 (8) 1	5 (14) 7	20 (21) 32
	Related TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	4 (4) 7
	Grade >=3 TEAE	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Dose 1 to Day 28 after Dose 2 or after Dose 1 (if no Dose 2)	Any TEAE	3 (25) 5	6 (50) 9	3 (25) 6	12 (33) 20	38 (40) 71
	Related TEAE	1 (8) 3	0 (0) 0	1 (8) 1	2 (6) 4	8 (8) 13
	Grade >=3 TEAE	0 (0) 0	1 (8) 1	2 (17) 2	3 (8) 3	4 (4) 4
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Any TESAE	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.

All = all younger and older participants; AE = adverse event; E = number of events; N = number of participants in the analysis set; n = number of participants with the specified characteristic; TEAE = treatment-emergent adverse event; TESAE = treatment-emergent serious adverse event; SAF = Safety Set.

Source: Table 14.3.1-3.1.3-3.

A summary of TEAEs is presented in Table 14.3.1-3.1.1-3. A summary of TEAEs in the completer set is presented in Table 14.3.1-3.1.2-3. A summary of TEAEs by SOC and PT in the completer set is presented in Table 14.3.1-3.3.1-3.

12.5.2 Analysis of adverse events

12.5.2.1 Frequency of TEAEs by SOC and PT

12.5.2.1.1 BNT162b1

12.5.2.1.1.1 Younger participants

Table 35 presents the frequency of participants with TEAEs by SOC and PT (Dose 1 up to Day 28 after Dose 2 or Dose 1). The most frequently reported SOCs (≥10%) were:

- "General disorders and administration site conditions" reported by 9 participants (11%):
  - Amongst which following PTs were most frequently reported: injection site reactions (n=5, 6%), influenza like illness and injection site hematoma (each, n=2, 2%).
- "Nervous system disorders" reported by 10 participants (12%):
  - Amongst which following PTs were most frequently reported: headache (n=4, 5%) and presyncope (n=3, 4%).
  - There were only single cases of hyperaesthesia and paraesthesia.
- "Respiratory, thoracic and mediastinal disorders" reported by 9 participants (11%):
  - Amongst which following PTs were most frequently reported: cough and oropharyngeal pain (each, n=4, 5%).

Table 35: Frequency of participants with TEAEs without AEs based on solicited reporting via diaries by SOC and PT – BNT162b1 younger participants (SAF)

System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Tachycardia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
Eye disorders	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	2 (2)
Asthenopia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	4 (5)
Dry mouth	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysphagia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	2 (17)	0 (0)	2 (17)	0 (0)	2 (17)	3 (25)	0 (0)	9 (11)
Fatigue	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza l ke illness	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
Injection site pain	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site paraesthesia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	2 (17)	0 (0)	5 (6)
Immune system disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Seasonal allergy	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	2 (17)	1 (8)	1 (8)	2 (17)	1 (8)	7 (8)
Conjunctivitis	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Fungal infection	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingivitis	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
Investigations	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	3 (4)
Gamma glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Lymphocyte count increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle strength abnormal	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Decreased appetite	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Musculoskeletal and connective tissue disorders	1 (8)	0 (0)	1 (8)	1 (8)	2 (17)	1 (8)	0 (0)	6 (7)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Muscle tightness	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (2)
Musculoskeletal chest pain	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	2 (2)
Myalgia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myosclerosis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
Nervous system disorders	3 (25)	0 (0)	2 (17)	1 (8)	1 (8)	1 (8)	2 (17)	10 (12)
Cervicobrachial syndrome	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	2 (17)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	4 (5)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Paraesthesia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	3 (4)
Taste disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	1 (8)	3 (4)
Depression	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (2)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	3 (25)	2 (17)	0 (0)	2 (17)	2 (17)	9 (11)
Cough	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
Dysphonia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	4 (5)
Rhinitis allergic	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (2)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Pruritus	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Surgical and medical procedures	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Papilloma excision	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N.

Adverse events are coded using MedDRA version 23.0.

This table excludes solicited event terms reported via diaries if its duration is ≤7days and start/end dates are complete. Due to partially missing dates and times this table still includes a couple of solicited event terms reported via diaries

AE = adverse event; N = number of participants in the analysis set; n = number of participants with the specified characteristic; PT = preferred term; SOC = system organ class; TEAE = treatment-emergent adverse event; SAF = Safety Set.

Source: modified from Table 14.3.1-3.4.1-1.

12.5.2.1.1.2 Older participants and all (younger and older) participants

Table 36 presents the frequency of participants with TEAEs by SOC and PT (Dose 1 up to Day 28 after Dose 2 or Dose 1). The most frequently reported SOCs were:

- "Respiratory, thoracic and mediastinal disorders" reported by 4 participants (11%). Amongst which the following PTs were most frequently reported: cough and oropharyngeal pain (each, n=2, 6%).
- Other PTs reported in more than one participant were bladder dysfunction (n=3, 8%), nasopharyngitis (n=2, 6%), and sleep disorder (n=2, 6%).
- The other SOCs were only reported by 1 or 2 participants each.

Table 36: Frequency of participants with TEAEs without AEs based on solicited reporting via diaries by SOC and PT – BNT162b1 older participants and all participants (SAF)

System organ class Preferred term	Older participants 10 µg (N=12) n (%)	Older participants 20 µg (N=12) n (%)	Older participants 30 µg (N=12) n (%)	Older participants Total (N=36) n (%)	All Total (N=120) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Ear pain	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	2 (17)	2 (6)	6 (5)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Dyspepsia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Infections and infestations	0 (0)	0 (0)	2 (17)	2 (6)	9 (8)
Nasopharyngitis	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Injury, poisoning and procedural complications	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Thermal burn	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	0 (0)	1 (8)	0 (0)	1 (3)	7 (6)
Musculoskeletal chest pain	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
Musculoskeletal pain	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Nervous system disorders	1 (8)	1 (8)	0 (0)	2 (6)	12 (10)
Migraine	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Syncope	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	2 (17)	2 (6)	5 (4)
Sleep disorder	0 (0)	0 (0)	2 (17)	2 (6)	4 (3)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Bladder dysfunction	0 (0)	0 (0)	3 (25)	3 (8)	3 (3)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Respiratory, thoracic and mediastinal disorders	2 (17)	0 (0)	2 (17)	4 (11)	13 (11)
Cough	2 (17)	0 (0)	0 (0)	2 (6)	6 (5)
Oropharyngeal pain	0 (0)	0 (0)	2 (17)	2 (6)	6 (5)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Alopecia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N.

Adverse events are coded using MedDRA version 23.0.

All = all younger and older participants; AE = adverse events; N = number of participants in the analysis set; n = number of participants with the specified characteristic; PT = preferred term; SOC = system organ class; TEAE = treatment-emergent adverse event; SAF = Safety Set.

Source: modified from Table 14.3.1-3.4.1-1.

The frequency of participants with TEAEs by SOC and PT is presented in Table 14.3.1-3.2.1-1.

12.5.2.1.2 BNT162b2

12.5.2.1.2.1 Younger participants

Table 37 presents the frequency of participants with TEAEs by SOC and PT (Dose 1 up to Day 28 after Dose 2 or Dose 1). The most frequently reported SOCs were:

- "General disorders and administration site conditions" reported by 8 participants (13%):
  - Amongst which the following PT was most frequently reported: vessel puncture site pain (n=2, 3%).

In the SOC of "Nervous system disorders" was only a single case of hypoaesthesia.

Table 37: Frequency of participants with TEAEs without AEs based on solicited reporting via diaries by SOC and PT – BNT162b2 younger participants (SAF)

System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Blood and lymphatic system disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
External ear inflammation	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Eye disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Blepharitis	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	1 (8)	2 (17)	1 (8)	0 (0)	0 (0)	4 (7)
Abdominal discomfort	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Haemorrhoids thrombosed	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Toothache	0 (0)	2 (17)	1 (8)	0 (0)	0 (0)	3 (5)
General disorders and administration site conditions	0 (0)	2 (17)	2 (17)	1 (8)	3 (25)	8 (13)
Injection site haematoma	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Malaise	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Vessel puncture site haematoma	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Infections and infestations	1 (8)	1 (8)	3 (25)	0 (0)	1 (8)	6 (10)
Cestode infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Gastroenteritis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Nasopharyngitis	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (3)
Oral herpes	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Rhinitis	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Tonsillitis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)

System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Injury, poisoning and procedural complications	3 (25)	3 (25)	1 (8)	0 (0)	0 (0)	7 (12)
Animal bite	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Arthropod sting	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin abrasion	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
Sunburn	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	3 (5)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Neck pain	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Nervous system disorders	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (3)
Anosmia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Reproductive system and breast disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Dysmenorrhoea	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	4 (7)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	4 (7)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version 23.0.
AE = adverse event; N = number of participants in the analysis set; n = number of participants with the specified characteristic; PT = preferred term; SOC = system organ class; TEAE = treatment-emergent adverse event; SAF = Safety Set.
Source: modified from Table 14.3.1-3.4.1-3.

12.5.2.1.2.2 Older participants and all (younger and older) participants

Table 38 presents the frequency of participants with TEAEs by SOC and PT (Dose 1 up to Day 28 after Dose 2 or Dose 1). The most frequently reported SOC was:

- "Musculoskeletal and connective tissue disorders" reported by 5 participants (14%):
  - Amongst which the following PT was most frequently reported: back pain (n=2, 6%).

The other SOCs were only reported by 1 or 2 participants.

Table 38: Frequency of participants with TEAEs without AEs based on solicited reporting via diaries by SOC and PT – BNT162b2 – Older participants and all participants (SAF)

System organ class Preferred term	Older participants 10 µg (N=12) n (%)	Older participants 20 µg (N=12) n (%)	Older participants 30 µg (N=12) n (%)	Older participants Total (N=36) n (%)	All Total (N=96) n (%)
Gastrointestinal disorders	0 (0)	2 (17)	0 (0)	2 (6)	6 (6)
Dyspepsia	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Toothache	0 (0)	1 (8)	0 (0)	1 (3)	4 (4)
General disorders and administration site conditions	1 (8)	0 (0)	1 (8)	2 (6)	10 (10)
Chest pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Injection site haematoma	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Injection site pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Injury, poisoning and procedural complications	0 (0)	2 (17)	0 (0)	2 (6)	9 (9)
Ankle fracture	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Face injury	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Investigations	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Amylase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Lipase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	2 (17)	1 (8)	2 (17)	5 (14)	6 (6)
Back pain	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
Muscle spasms	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Tendon pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Nervous system disorders	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal colic	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	0 (0)	1 (3)	5 (5)
Painful respiration	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Seborrhoeic dermatitis	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version 23.0.

All = all younger and older participants; AE = adverse event; N = number of participants in the analysis set; n = number of participants with the specified characteristic; PT = preferred term; SOC = system organ class; TEAE = treatment-emergent adverse event; SAF = Safety Set.

Source: modified from Table 14.3.1-3.4.1-3.

The frequency of participants with TEAEs by SOC and PT is presented in Table 14.3.1-3.2.1-3.

12.5.2.2 Intensity of TEAEs

12.5.2.2.1 BNT162b1

In the younger participants group, the most frequently reported SOC with Grade ≥3 TEAEs and related to IMP was “General disorders and administration site conditions” (Table 14.3.1-3.2.3-1 and Table 14.3.1-3.2.4-1).

- Within 7 d after Dose 1, 1 participant (1%): PT reported was pyrexia (n=1, 8%) in 60 µg group.
- Within 28 d after Dose 1 or up to Dose 2, 1 participant (1%): PT reported was pyrexia (n=1, 8%) in 60 µg group and headache (n=1, 8%) in 60 µg group.
- Within 7 d after Dose 2, 3 participants (2 participants in 50 µg group and 1 in 10 µg group): PT reported was influenza like illness (n=3, 4%).
- Within 28 d after Dose 2, 3 participants (2 participants in 50 µg group and 1 in 10 µg group): PT reported was influenza like illness (n=3, 4%).
- Within 28 d after Dose 1 or Dose 2, 4 participants (5%): PTs reported were influenza like illness (n=2 in 50 µg group and n=1 in 10 µg) and pyrexia (n=1, 8%) in 60 µg group.

While from the SOC “Nervous system disorders”; Grade ≥3 headache was experienced by 1 participant in the 20 µg group, which was assessed as not related.

In the older participants group, no TEAEs with Grade ≥3 and related to IMP were reported (Table 14.3.1-3.2.3-1 and Table 14.3.1-3.2.4-1). the most frequently reported SOC with Grade ≥3 TEAEs was “Nervous system disorders”.

- Within 28 d after Dose 1, 1 participant (1%): PT reported was migraine (n=1, 8%) in 10 µg group and 1 participant: PT reported was syncope (n=1, 8%) in the 20 µg group.
- Within 28 d after Dose 1 or Dose 2, 1 participant (1%): PT reported was migraine (n=1, 8%) in 10 µg group and 1 participant: PT reported was syncope (n=1, 8%) in the 20 µg group.

The frequency of participants with TEAEs by worst grade, SOC and PT is presented in Table 14.3.1-3.5.1-1.

12.5.2.2.2 BNT162b2

In the younger participants group, the most frequently reported SOC with Grade ≥3 TEAEs was “Musculoskeletal and connective tissue disorder” (Table 14.3.1-3.2.3-3).

- The most frequently reported PT was neck pain (n=1, 2%) in the 10 µg group.

None of the Grade ≥3 TEAEs were assessed as related to the IMP (Table 14.3.1-3.2.4-3).

In the older participants group, the most frequently reported SOC with Grade ≥3 TEAEs was “Nervous system disorders” (Table 14.3.1-3.2.3-3).

- The reported PTs were headache in 1 participant (3%) and orthostatic intolerance in 1 participant (3%) in the 30 µg group.

None of the Grade ≥3 TEAEs were assessed as related to the IMP (Table 14.3.1-3.2.4-3).

The frequency of participants with TEAEs by worst grade, SOC and PT is presented in Table 14.3.1-3.5.1-3.

12.5.2.3 Relationship of TEAEs to IMP

12.5.2.3.1 BNT162b1

In the younger participants, in the Safety Set, Dose 2 up to Day 28 after Dose 2, the most frequently reported related SOCs were:

- "General disorders and administration site conditions" were reported by 40 participants (48%):
  - Amongst which the following PTs were most frequently reported: influenza like illness (n=32, 38%), injection site reaction (n=29, 35%), and injection site discomfort (n=7, 8%) (Table 14.3.1-3.2.2-1).
- "Nervous system disorders" reported by 16 participants (19%):
  - Amongst which following PT was most frequently reported headache (n=11, 13%) (Table 14.3.1-3.2.2-1).
- "Musculoskeletal and connective tissue disorders" reported by 5 participants (6%):
  - Amongst which following PTs was most frequently reported myalgia (n=2, 2%), (Table 14.3.1-3.2.2-1).
- In the older participants, in the Safety Set, Dose 2 up to Day 28 after Dose 2, one related TEAE was reported in the 30 µg group in each of the following SOCs: "Ear and labyrinth disorders", Gastrointestinal disorders", "and "Urinary disorders" (Table 14.3.1-3.2.2-1).

12.5.2.3.2 BNT162b2

In the younger participants, in the Safety Set, Dose 2 up to Day 28 after Dose 2, the most frequently reported related SOC was:

- "General disorders and administration site conditions" reported by 10 participants (17%):
  - Amongst which the most frequently reported PTs were injection site reaction (n=10, 17%) and influenza like illness (n=4, 7%) (Table 14.3.1-3.2.2-3).
- In the older participants, in the Safety Set, Dose 2 up to Day 28 after Dose 2, the only reported related SOC was:
- "Vascular disorders" reported by 1 participant (3%) with the PT of hot flush.

12.5.2.4 Outcome of TEAEs

None of the reported TEAEs were unresolved (Table 14.3.1-3.2.7-1 [BNT162b1] and Table 14.3.1-3.2.7-3 [BNT162b2]).

12.5.3 Listing of AEs by participant

Listings of AEs by participant are presented in Listing 16.2.3-1.5-1 (BNT162b1) and Listing 16.2.3-1.5-3 (BNT162b2).

12.6 Deaths, other SAEs, and other significant AEs

12.6.1 BNT162b1

12.6.1.1 Younger participants

One participant discontinued due to a moderate AE (malaise) from the study; a detailed narrative is given below. There were no deaths (Table 14.3.1-3.2.7-1), other TESAEs (Table 14.3.1-3.2.5-1, Table 14.3.1-3.2.6-1, and Table 14.3.1-3.7.1-1), TEAEs of special interest (Table 14.3.1-3.1.4-1), or other significant AEs, reported at the cut-off dates for this report.

Participant 10010 was a 53-yr-old White female (Listing 16.2.1-5-1). The participant was enrolled into the study on 22 APR 2020 and received Dose 1 (10 µg) on 24 APR 2020 (Listing 16.2.1-1-1). On the same Day (24 APR 2020) the participant experienced mild tiredness and fatigue. Both the events resolved (tiredness and fatigue) without medication on 07 MAY 2020 and were assessed as related to the IMP by the investigator. On 12 MAY 2020 the participant experienced malaise, myalgia, chills, and pyrexia (fever up to 39.3°C). The events (malaise, chills, and pyrexia) were moderate in severity, while myalgia was mild in severity. These events were assessed as not related to the IMP by the investigator. The event (chills) resolved on 13 MAY 2020 without medication while the event (pyrexia) resolved on 14 MAY 2020 with medication. The events (malaise and myalgia) resolved with medication on 16 MAY 2020 (Listing 16.2.3-1.3-1). On 19 MAY 2020, the participant withdrew from the study due to the event (malaise) (Listing 16.2.3-1.3-1 and Listing 16.2.1-3-1).

One participant discontinued the study IMP due to dose limiting toxicity; a detailed narrative for this participant is given below.

Participant 10075 was a 27-yr-old White female (Listing 16.2.1-5-1). The participant was enrolled into the study on 11 May 2020 and received Dose 1 (60 µg) on 22 MAY 2020 (Listing 16.2.1-1-1). On the same Day (22 MAY 2020) the participant experienced mild flatulence and ear pain, moderate headache, influenza like illness and injection site reactions and severe pyrexia (39.2°C). All these events were assessed as TEAEs and related to the IMP. The event pyrexia qualified as a dose limiting toxicity. It was determined the participant should not receive their Dose 2 and as a result the IMP was withdrawn on the same day. The events (flatulence, pyrexia, and ear pain) resolved on 24 May 2020 without medication, except for pyrexia, which resolved with medication. The event (influenza like illness) resolved on 26 MAY 2020 without medication. The event (headache) resolved on 27 MAY 2020 with medication, while injection site reactions resolved on 28 MAY 2020 without medication (Listing 16.2.3-1.3-1).

12.6.1.2 Older participants and all (younger and older) participants

In the Safety Set, Dose 1 up to Dose 2 or Day 28 after Dose 1, 1 participant (8%) had a serious not related TEAE in the SOC of “Nervous system disorders”. This was an event of syncope in the 20 µg group (Table 14.3.1-3.2.5-1, Table 14.3.1-3.2.6-1, and Listing 14.3.1-3.7.1-1). A detailed narrative is given below.

There were no deaths (Table 14.3.1-3.2.7-1), TEAEs of special interest (Table 14.3.1-3.1.4-1), or other significant AEs, reported at the cut-off dates for this report.

Participant 20242 was a 70-yr-old White female (Listing 16.2.1-5-1). The participant was enrolled into the study on 28 AUG 2020 and received Dose 1 (20 µg) on 09 SEP 2020 (Listing 16.2.1-1-1). On 18 SEP 2020, the participant experienced moderate left costal arch and shoulder pain which is ongoing and medication is provided. This event was assessed as a TEAE but not related to the IMP. On 20 SEP 2020, the participant experienced treatment-emergent SAE of severe syncope which was not related to IMP. On 24 SEP 2020 the IMP was withdrawn (Dose 2 was not given).

12.6.2 BNT162b2

12.6.2.1 Younger participants

One participant discontinued due to a moderate AE (nasopharyngitis) from the study and detailed narrative is given below. There were no deaths (Table 14.3.1-3.2.7-3), other TESAEs (Table 14.3.1-3.2.5-3, Table14.3.1-3.2.6-3, and Listing 14.3.1-3.7.1-3), TEAEs of special interest (Table 14.3.1-3.1.4-3), or other significant AEs, reported at the cut-off dates for this report.

Participant 20116 was a 23-yr-old White female (Listing 16.2.1-5-3). The participant was enrolled into the study on 20 MAY 2020 and received Dose 1 (10 µg) on 18 JUN 2020 (Listing 16.2.1-1-3). On 21 JUN 2020 the participant experienced mild external ear inflammation which resolved with medication on 28 JUN 2020. The event (external ear inflammation) was assessed as a TEAE but not related to the IMP. On 04 JUL 2020, the participant experienced moderate nasopharyngitis which resolved with medication on 22 JUL 2020. This event was assessed as a TEAE but not related to the IMP. Due to the event (nasopharyngitis) the participant withdrew from the study on 16 JUL 2020 (Listing 16.2.3-1.3-3).

12.6.2.2 Older participants and all (younger and older) participants

In the Safety Set, Dose 1 up to Dose 2 or Day 28 after Dose 1, one participant (8%) had a serious not related TEAE in the SOC of “Injury, poisoning and procedural complications”. This was an event of ankle fracture in the 20 µg group (Table 14.3.1-3.2.5-3, Table 14.3.1-3.2.6-3, and Listing 14.3.1-3.7.1-3). A detailed narrative is given below.

There were no deaths (Table 14.3.1-3.2.7-3), TEAEs of special interest (Table 14.3.1-3.1.4-3), or other significant AEs, reported at the cut-off dates for this report.

Participant 20215 was an 80-yr-old White female (Listing 16.2.1-5-3). The participant was enrolled into the study on 11 AUG 2020 and received Dose 1 (20 µg) on 01 SEP 2020 and Dose 2 on 22 SEP 2020 (Listing 16.2.1-1-3). On 14 OCT 2020, the participant experienced a moderate treatment-emergent SAE of ankle fracture which was not related to IMP. Treatment was provided and the participant is recovering (Listing 16.2.3-1.5-3).

12.7 Clinical laboratory evaluation

12.7.1 Listing of individual laboratory measurements by participant and each abnormal laboratory value

A listing of individual laboratory measurements by participant and each abnormal laboratory value is provided in Listing 16.2.3-2.2-1 (BNT162b1) and Listing 16.2.3-2.2-3 (BNT162b2).

12.7.2 Evaluation of each laboratory parameter

12.7.2.1 Hematology

The descriptive statistics for hematology parameters are presented in Table 14.3.2-2.1.1-1 (BNT162b1) and Table 14.3.2-2.1.1-3 (BNT162b2).

Changes from baseline in lymphocyte (low) count were reported in all dose groups after 48 h of dosing with both the IMPs (51 participants in BNT162b1 younger participants [n=6 in 10 µg, n=10 in 20 µg and 30 µg, n=11 in 50 µg, and n=10 in 60 µg groups respectively], 28 participants in BNT162b1 older participants [n=7 in 10 µg, n=10 in 20 µg and n=11 in 30 µg groups respectively), 16 participants in BNT162b2 younger participants [n=2 in 10 µg, n=7 in 20 µg, n=6 in 30 µg groups, respectively]) and 14 participants in the BNT162b2 older participants [n=3 in 10 µg, n=2 in 20 µg, n=9 in 30 µg groups, respectively]) as a pharmacodynamics effect (Table 14.3.2-2.5.1-1 and Table 14.3.2-2.5.1-3, respectively). However, their values came back to normal at the subsequent visit without any clinical consequence and without sequelae (Table 39 [BNT162b1]) and (Table 40 [BNT162b2]).

One participant (10018) in the BNT162b1 younger participants group (1 µg) reported high lymphocyte count (4.33 x 10^9/L; normal 1.22 to 3.56 x 10^9/L) on Day 29 which was assessed as related mild TEAE and also as clinically significant event. The event resolved 8 d after the last dose (17 JUN 2020) without any medication (Table 14.3.2-2.5.1-1, Listings 16.2.3-1.3-1, 16.2.3-1.5-1, and 16.2.3-2.2-1 [BNT162b1]).

Table 39: Laboratory: Descriptive statistics, continuous (Hematology) – BNT162b1 (SAF)

			Younger participants							
Parameter [Unit]	**Visit**		**1 µg (N=12)**	**3 µg (N=12)**	**10 µg (N=12)**	**20 µg (N=12)**	**30 µg (N=12)**	**50 µg (N=12)**	**60 µg (N=12)**	**Total (N=84)**
Lymphocytes (Blood) [10^9/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	1.874 (0.559)	1.847 (0.540)	2.027 (0.558)	1.772 (0.488)	2.016 (0.477)	1.896 (0.444)	1.743 (0.389)	1.882 (0.490)
		Min	1.10	0.98	0.83	1.01	0.98	1.11	1.10	0.83
		Median	1.775	1.790	2.030	1.710	2.060	1.880	1.700	1.880
		Max	3.08	3.22	3.10	2.87	2.81	2.55	2.56	3.22
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	1.838 (0.534)	1.608 (0.508)	1.942 (0.535)	1.703 (0.518)	1.908 (0.248)	1.784 (0.414)	1.704 (0.337)	1.784 (0.452)
		Min	1.13	0.98	0.78	1.11	1.53	1.10	1.19	0.78
		Median	1.745	1.435	2.015	1.565	1.900	1.660	1.645	1.710
		Max	2.80	2.86	2.86	2.71	2.24	2.69	2.48	2.86
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	1.570 (0.315)	1.376 (0.399)	1.155 (0.491)	0.913 (0.256)	0.922 (0.254)	0.684 (0.205)	0.748 (0.269)	1.053 (0.438)
		Min	1.17	0.74	0.40	0.65	0.50	0.40	0.43	0.40
		Median	1.485	1.345	1.135	0.850	0.905	0.655	0.665	0.950
		Max	2.05	2.26	2.12	1.53	1.35	1.10	1.29	2.26
	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	1.707 (0.477)	1.838 (0.597)	1.938 (0.507)	1.834 (0.711)	1.925 (0.485)	1.813 (0.236)	1.772 (0.517)	1.832 (0.508)
		Min	1.08	1.33	0.88	1.26	1.24	1.39	0.97	0.88
		Median	1.645	1.705	1.895	1.625	1.920	1.770	1.655	1.760
		Max	2.85	3.38	2.98	3.71	2.97	2.16	2.84	3.71

Parameter [Unit]	Visit		Older participants 10 µg (N=12)	Older participants 20 µg (N=12)	Older participants 30 µg (N=12)	Older participants Total (N=36)	All Total (N=120)
Lymphocytes (Blood) [10^9/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	1.764 (0.428)	1.654 (0.437)	1.663 (0.403)	1.694 (0.414)	1.825 (0.474)
		Min	0.83	1.05	0.96	0.83	0.83
		Median	1.780	1.760	1.710	1.735	1.820
		Max	2.35	2.35	2.52	2.52	3.22
	Day 1	n	11	10	12	33	117
		Mean (SD)	1.761 (0.411)	1.532 (0.515)	1.693 (0.375)	1.667 (0.430)	1.751 (0.447)
		Min	0.76	0.68	1.32	0.68	0.68
		Median	1.820	1.410	1.630	1.690	1.710
		Max	2.20	2.38	2.57	2.57	2.86
	Day 2	n	12	12	12	36	120
		Mean (SD)	1.026 (0.316)	0.869 (0.294)	0.773 (0.204)	0.889 (0.288)	1.004 (0.405)
		Min	0.61	0.47	0.47	0.47	0.40
		Median	1.000	0.860	0.750	0.850	0.935
		Max	1.67	1.41	1.14	1.67	2.26
	Day 8	n	12	12	12	36	120
		Mean (SD)	1.748 (0.414)	1.521 (0.443)	1.863 (0.490)	1.711 (0.460)	1.796 (0.495)
		Min	0.92	0.70	1.14	0.70	0.70
		Median	1.665	1.550	1.760	1.630	1.725
		Max	2.49	2.25	2.79	2.79	3.71

SD is only calculated if values of at least 3 participants are available.

All = all younger and older participants; Min = minimum; max = maximum; N = number of participants in the analysis set; n = number of participants with data available; SD = standard deviation.

Source: modified from Table 14.3.2-2.1.1-1.

Table 40: Laboratory: Descriptive statistics, continuous (Hematology) – BNT162b2 (SAF)

			Younger participants					
Parameter [Unit]	**Visit**		**1 µg (N=12)**	**3 µg (N=12)**	**10 µg (N=12)**	**20 µg (N=12)**	**30 µg (N=12)**	**Total (N=60)**
Lymphocytes (Blood) [10^9/L]	Day -30 to 0	n	12	9	12	12	12	57
		Mean (SD)	1.858 (0.438)	1.721 (0.333)	1.823 (0.285)	1.695 (0.456)	1.780 (0.395)	1.778 (0.381)
		Min	1.29	1.15	1.28	0.92	1.17	0.92
		Median	1.860	1.820	1.730	1.775	1.795	1.800
		Max	2.67	2.12	2.25	2.51	2.41	2.67
	Day 1	n	11	12	12	12	11	58
		Mean (SD)	1.807 (0.555)	1.577 (0.385)	1.678 (0.355)	1.515 (0.442)	1.618 (0.320)	1.636 (0.415)
		Min	1.26	0.91	0.90	0.81	1.21	0.81
		Median	1.740	1.550	1.755	1.590	1.560	1.605
		Max	3.20	2.16	2.18	2.21	2.40	3.20
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	1.834 (0.332)	1.612 (0.349)	1.363 (0.283)	1.197 (0.357)	1.197 (0.319)	1.440 (0.405)
		Min	1.33	1.10	0.86	0.73	0.88	0.73
		Median	1.825	1.670	1.395	1.115	1.115	1.510
		Max	2.60	2.13	1.74	1.70	1.83	2.60
	Day 8	n	12	12	11	12	11	58
		Mean (SD)	1.823 (0.422)	1.633 (0.428)	1.776 (0.288)	1.589 (0.463)	1.690 (0.362)	1.701 (0.396)
		Min	1.07	0.86	1.30	0.93	1.24	0.86
		Median	1.770	1.705	1.820	1.475	1.690	1.700
		Max	2.84	2.29	2.16	2.55	2.42	2.84

Parameter [Unit]	Visit		Older participants 10 µg (N=12)	Older participants 20 µg (N=12)	Older participants 30 µg (N=12)	Older participants Total (N=36)	All Total (N=96)
Lymphocytes (Blood) [10^9/L]	Day -30 to 0	n	12	12	12	36	93
		Mean (SD)	1.660 (0.488)	1.962 (0.715)	1.494 (0.453)	1.705 (0.582)	1.750 (0.467)
		Min	1.09	0.88	0.95	0.88	0.88
		Median	1.490	1.735	1.405	1.625	1.720
		Max	2.43	3.39	2.41	3.39	3.39
	Day 1	n	12	12	12	36	94
		Mean (SD)	1.517 (0.373)	1.763 (0.810)	1.491 (0.451)	1.590 (0.574)	1.619 (0.480)
		Min	0.93	0.53	0.81	0.53	0.53
		Median	1.495	1.635	1.445	1.510	1.565
		Max	2.01	3.83	2.33	3.83	3.83
	Day 2	n	12	12	12	36	96
		Mean (SD)	1.407 (0.391)	1.558 (0.541)	0.988 (0.267)	1.318 (0.472)	1.394 (0.433)
		Min	0.81	0.78	0.72	0.72	0.72
		Median	1.495	1.445	0.860	1.290	1.390
		Max	2.18	2.70	1.48	2.70	2.70
	Day 8	n	11	12	12	35	93
		Mean (SD)	1.637 (0.447)	1.958 (0.784)	1.662 (0.540)	1.755 (0.611)	1.722 (0.486)
		Min	0.99	0.80	0.86	0.80	0.80
		Median	1.640	1.855	1.600	1.680	1.700
		Max	2.33	3.43	2.63	3.43	3.43

SD is only calculated if values of at least 3 participants are available.

All = all younger and older participants; Min = minimum; max = maximum; N = number of participants in the analysis set; n = number of participants with data available; SD = standard deviation.

Source: modified from Table 14.3.2-2.1.1-3.

12.7.2.2 Clinical chemistry

The descriptive statistics for chemistry parameters is presented in Table 14.3.2-2.1.2-1 (BNT162b1) and Table 14.3.2-2.1.2-3 (BNT162b2).

Changes from baseline were small in all dose groups following the administration of both the IMPs. Likewise, the changes from baseline did not indicate a particular trend in the time course of all clinical chemistry parameters, except for CRP in both the IMP groups in the younger participants group, as a pharmacodynamics effect. Elevated values were reported by 2 participants (in 30 µg and 50 µg groups) at 48 h (23.7 mg/L and 22.3 mg/L; [normal range: ≤4.9 mg/L]) as compared to Day 1 (<0.3 mg/L and 2.0 mg/L, respectively) in the BNT162b1 group (Table 14.3.2-2.5.2-1 and Listing 16.2.3-2.2-1). In the BNT162b2 group, one participant (in the 1 µg group) had elevated CRP values at Day 8 (31.6 mg/L) as compared to Day 1 (1.0 mg/L; normal range: ≤4.9 mg/L) (Table 14.3.2-2.5.2-3 and Listing 16.2.3-2.2-3). However, their values came back to normal at the subsequent visit without any clinical consequence.

In the older participants group, no elevated values of CRP were seen.

12.7.2.3 Urinalysis

The descriptive statistics for urinalysis parameters (continuous) is presented in Table 14.3.2-2.1.3-1 (BNT162b1) and Table 14.3.2-2.1.3-3 (BNT162b2). The descriptive statistics for urinalysis parameters (categorical) is presented in Table 14.3.2-2.1.4-1 (BNT162b1) and Table 14.3.2-2.1.4-3 (BNT162b2).

There were a few abnormal urinalysis parameters but none of them were clinically significant except for one (Table 14.3.2-2.5.3-1 [BNT162b1] and Table 14.3.2-2.5.3-3 [BNT162b2]). One younger participant in the 1 µg group had an elevated number of leukocytes at Day 50.

12.7.3 Individual clinically relevant abnormalities in clinical laboratory values

There were a few abnormal hematology parameters but none of them were clinically relevant abnormalities (Table 14.3.2-2.5.1-3 [BNT162b2]), except for one younger participant in the BNT162b1 (1 µg) who had a high lymphocyte count (4.33 x 10^9/L; normal 1.22- 3.56 x 10^9/L) on Day 29, 7 days after Dose 2, which was assessed as related TEAE and also as clinically significant event. The event resolved 8 d after the last dose (17 JUN 2020) without any medication (Table 14.3.2-2.5.1-1, Listing 16.2.3-1.3-1 and 16.2.3-2.2-1 [BNT162b1]).

A few abnormal chemistry parameters were reported but none of them were clinical relevant abnormalities, except for CRP reported on Day 2 by 2 participants (3%) (n=1 each in 30 µg and 50 µg groups) for BNT162b1 (Table 14.3.2-2.5.2-1) and on Day 8 by one participant (2%) (n=1 in 1 µg group) for BNT162b2 (Table 14.3.2-2.5.2-3).

There were a few abnormal urinalysis parameters but none of them were clinically relevant abnormalities (Table 14.3.2-2.5.3-1 [BNT162b1] and Table 14.3.2-2.5.3-3 [BNT162b2]).

12.8 Vital signs, physical findings, and other observations related to safety

12.8.1 Vital signs

Descriptive statistics of vital signs data is given in Table 14.3.2-3.1-1 (BNT162b1) and Table 14.3.2-3.1-3 (BNT162b2).

A few abnormal vital signs were reported but none of them were clinical relevant abnormalities (Table 14.3.2-3.3-3 [BNT162b2]), except for mild or moderate elevated body temperature reported on Day 2 by 5 younger participant participants (6%) in (n=1 each in 30 µg and 50 µg groups and n=3 in 60 µg group) BNT162b1 group (Table 14.3.2-3.3-1). The events were assessed as related TEAEs. The elevated body temperature values came back to normal at the subsequent visit with medication (Table 14.3.2-3.3-1 and Listing 16.2.3-2.3-1).

All vital signs data is given in Listing 16.2.3-2.3-1 (BNT162b1) and Listing 16.2.3-2.3-3 (BNT162b2).

12.8.2 12-lead electrocardiograms

Normal ECGs were a requirement for enrollment into this study. As judged by the investigator, no participants presented clinically significant ECG findings.

ECG data will be provided in a later update on this study.

12.8.3 Physical examination

Normal complete physical examinations were a requirement for enrollment into this study. As judged by the investigator, no enrolled participants presented clinically significant physical examinations findings at screening or when assessed during the ongoing study.

All physical examination data will be provided in a later update on this study.

12.8.4 Pregnancy

By the cut-off date for this report, there were no pregnancies reported in study participants (or their partners) in dose groups with BNT162b1 or BNT162b2 dosing.

12.9 Safety conclusions

12.9.1 BNT162b1

- In the younger participants group, 84 participants received Dose 1 while 69 participants received Dose 2. In the older participants group, 36 participants received Dose 1 and 35 participants received Dose 2.
- Generally, good tolerability was observed. The majority of events reported were reactogenicity symptoms compared to TEAEs which were anticipated for IM-administered vaccines, typically with an onset within first 24 h post-dose.
- In the younger participants group, 72 participants (86%) experienced mild solicited local reactions, of which 15 participants (18%) experienced Grade ≥3 solicited local reactions with a possible dose dependency between 10 µg (1 participant) and 20 µg and 30 µg (2 and 5 participants) doses. The most frequently reported solicited local reaction was tenderness (n=70, 83%), followed by pain (n=67, 80%).
  In the older participants group, 30 participants (83%) reported any local reaction at any dose in the combined interval. No participants reported a Grade ≥3 local reaction. The most frequently reported solicited local reactions of any severity were tenderness (n=28, 78%) and pain (n=27, 75%).
- In the younger participants group, 77 participants (92%) experienced solicited systemic reactions, of which 37 participants (44%) experienced Grade ≥3 solicited systemic reactions with a possible dose dependency between 10 µg (6 participants), 20 µg (5 participants), 30 µg (6 participants), and 50 µg (8 participants) and 60 µg (8 participants) dose groups. The most frequently reported solicited systemic reaction was fatigue (n=68, 81%), headache (n=66, 79%), myalgia (n=51, 61%), malaise (n=50, 60%), and chills (n=47, 56%).
  In the older participants group, 33 participants (92%) reported any systemic reaction

at any dose, of which 10 (28%) participants reported Grade ≥3 with a possible dose dependency between 10 µg and 20 µg (2 and 3 participants) and 30 µg (5 participants), dose groups. The most frequently reported solicited systemic reactions of any severity were fatigue (n=27, 75%), and myalgia (n=18, 50%).

- In the younger participants group, 30 participants (43%) experienced in total 67 TEAEs, of which 39 events were related TEAEs. The most frequently reported TEAEs were headache, influenza like illness, injection site reactions, cough, and oropharyngeal pain.
  In the older participants group, 12 participants (34%) experienced in total 21 TEAEs of which 9 were related TEAEs. The most frequently reported TEAEs were cough and oropharyngeal pain.
- In the younger participants group, the most frequent Grade ≥3 TEAEs was influenza like illness experienced by 3 participants which was assessed as related TEAE by the investigator.
- One participant in the younger participants group discontinued the study due to malaise which was moderate in severity and assessed as not related to the IMP.
- There were no, deaths, TEAEs of special interest, or pregnancies that led to withdrawal. One participant in the older participants group treated with 20 µg had a serious not related TEAE (severe syncope) and the IMP was withdrawn (Dose 2 was not given).
- Changes from baseline in lymphocyte (low) count were reported in all dose groups after 48 h of dosing with both the IMPs (51 participants in the younger participants group and 28 participants in the older participants group).
- There were no clinically relevant findings in urinalysis parameters.
- Two participants in the younger participants group experienced high CRP 48 h post-dose. However, these values came back to normal without clinical consequence at the subsequent visit.
- Five participants (8%) experienced elevated body temperature on Day 2, which was assessed as related TEAE and the event resolved at the subsequent visit with medication.

12.9.2 BNT162b2

- In the younger participants group, 60 participants received Dose 1, while 58 participants received Dose 2. In the older participants group, 36 participants received both Dose 1 and Dose 2.
- Generally, good tolerability was observed. The majority of events reported were reactogenicity symptoms compared to TEAEs which were anticipated for IM-administered vaccines, typically with an onset within first 24 h post-dose.
- In the younger participants group, 52 participants (87%) experienced solicited local reactions, of which none of the participants reported Grade ≥3 local reactions. The most frequently reported solicited local reactions were mild tenderness and mild pain

(each, n=45, 75%).
In the older participants group, 31 participants (86%) reported any local reaction at any dose, of which 2 participants (6%) reported Grade ≥3 local reactions. The most frequently reported solicited local reaction of any severity was mild tenderness (n=24, 67%) followed by mild pain (n=22, 61%).

- In the younger participants group, 53 participants (88%) experienced solicited systemic reactions, of which 6 participants (10%) reported Grade ≥3 solicited systemic reactions with a possible dose dependency between 10 µg and higher doses. The most frequently reported solicited systemic reactions were fatigue (n=40, 67%), followed by headache (n=32, 53%), malaise (n=24, 40%), and myalgia (n=23, 38%).
  In the older participants group, 72% of participants reported any systemic reaction at any dose, of which 4 participants reported Grade ≥3 solicited systemic reactions. The most frequently reported solicited systemic reactions of any severity were fatigue (n=20, 56%), followed by headache (n=17, 47%), malaise (n=12, 33%), and myalgia (n=12, 33%).
- The frequency of local and systemic reactogenicity was generally lower for BNT162b2 compared to BNT162b1. BNT162b2 generally had a milder and therefore more favorable reactogenicity profile than BNT162b1 across dose levels.
- In the younger participants group, 26 participants (43%) experienced in total 51 TEAEs, of which 9 events were related TEAEs. The most frequently reported TEAE was vessel puncture site pain.
  In the older participants group, 12 participants (33%) experienced in total 20 TEAEs of which 4 events were related TEAEs. The most frequently reported TEAE was back pain.
- In the younger participants group, Grade ≥3 TEAEs were experienced by 1 participant (2%) (neck pain) which was assessed as not related Grade ≥3 TEAE by the investigator. In the older participants group, Grade ≥3 TEAEs were experienced by 1 participant (2%) (orthostatic intolerance) which was assessed as not related Grade ≥3 TEAE by the investigator.
- One participant in the younger participants group discontinued the study due to nasopharyngitis which was moderate in severity and assessed as not related to the IMP.
- There were no deaths, TEAEs of special interest, or pregnancies that led to withdrawal reported. One participant in the older participants group treated with 20 µg had a serious not related TEAE (ankle fracture).
- Changes from baseline in lymphocyte (low) count were reported in all dose groups after 48 h of dosing with both the IMPs (16 participants in the younger participants group and 14 participants in the older participants group). These values came back to normal values without any clinical consequence at the subsequent visit.

- There were no clinically relevant changes in urinalysis or in clinical chemistry. One participant in the younger participants group had high CRP 48 h value post-dose that was back at normal value without clinical consequence at the subsequent visit.
- There were no clinically relevant changes in vital signs during the study.

13 DISCUSSION AND OVERALL CONCLUSIONS

This was an open-label, multi-site, Phase I/II, 2-part, dose-escalation, first in human study evaluating the safety, tolerability, and immunogenicity of prophylactic BNT162 vaccines against COVID-19 in healthy participants after two doses of IMP given ~21 d apart.

There were no changes in the conduct of the study considered by the sponsor to either impact the study objectives or to have compromised participant safety. The IMP was administered by a physician, and thus the extent of exposure of participants to the IMP was as expected and as stipulated in the protocol. There were some protocol deviations, none of these protocol deviations were considered to have affected the participant's safety or the objectives of the study.

This report presents data for a population appropriate for a Phase I/II study with the first in human dosing with BNT162b1 and BNT162b2, i.e., healthy younger participants (aged between 18 and 55 yrs), and data from a population of healthy older participants (aged between 56 and 85 yrs) who are at highest risk for COVID-19.

13.1 Safety

Primary safety endpoint

For BNT162b1, in the younger participants group, a total of 72 participants (86%) reported solicited local reactions, of which 15 participants (18%) reported Grade ≥3 solicited local reactions with a possible dose dependency between 10 µg (1 participant) and 20 µg and 30 µg (2 and 5 participants) doses. A total of 77 participants (92%) reported solicited systemic reactions, of which 37 participants (44%) reported Grade ≥3 solicited systemic reactions. A total of 38 participants (45%) reported in total 83 TEAEs, of which 51 events were related TEAEs. Two participants reported any Grade ≥3 TEAEs. One participant who received (10 µg) vaccine withdrew from the study due to moderate malaise. There were no TESAEs or deaths.

In the older participants group, 30 participants (83%) reported any local reaction at any dose in the combined interval. No participants reported a Grade ≥3 local reaction. A total of 33 participants (92%) reported any systemic reaction at any dose, of which 10 (28%) participants reported Grade ≥3. A total of 13 participants (36%) experienced in total 24 TEAEs of which 9 were related TEAEs. Four participants reported any Grade ≥3 TEAEs. One participant in the older participants group had a serious not related TEAE (severe syncope). The IMP was withdrawn (Dose 2 was not given).

For BNT162b2, in the younger participants group, a total of 52 participants (87%) reported solicited local reactions. A total of 53 participants (88%) reported solicited systemic reactions, of which 6 participants (10%) reported Grade ≥3 solicited systemic reactions. A total of 26 participants (43%) reported in total 51 TEAEs, of which 6 events were related

TEAEs. Grade ≥3 TEAE was reported by one participant (2%) which was assessed as not related by the investigator. One participant who received (10 µg) vaccine withdrew from the study due to moderate nasopharyngitis.

In the older participants group, 31 participants (86%) reported any local reaction at any dose, of which 2 participants (6%) reported Grade ≥3 local reactions. 72% of participants reported any systemic reaction at any dose, of which 4 participants reported Grade ≥3 solicited systemic reactions. A total of 12 participants (33%) experienced in total 20 TEAEs of which 4 events were related TEAEs. Grade ≥3 TEAEs were experienced by 3 participants (2%) (orthostatic intolerance) which was assessed as not related Grade ≥3 TEAE by the investigator. One participant in the older participants group had a serious not related TEAE (ankle fracture).

The frequency of local and systemic reactogenicity was generally lower for BNT162b2 compared to BNT162b1. BNT162b2 generally had a milder and therefore more favorable reactogenicity profile than BNT162b1 across dose levels.

Additionally, the frequency of local and systemic reactogenicity as well as TEAEs was lower in the older participants group compared to the younger participants group as shown in Table 41.

Generally, good tolerability was observed for both IMPs. Overall, many of the reported AEs appear to represent reactogenicity events anticipated for IM-administered vaccines, typically with an onset within first 24 h post dosing. All TEAEs / reactogenicity symptoms resolved spontaneously, mostly within 24 h of onset, and were managed with simple measures and widely available medications such as analgesics and anti-pyretics (e.g., paracetamol). The observed reactogenicity was mild or moderate in severity. Reactogenicity was generally higher after the second dose, but symptoms resolved quickly over the course of a few days. There were no deaths, or TEAEs of special interest reported in this study. In the older participants group, one participant treated with 20 µg BNT162b1 and one participant treated with 20 µg BNT162b2 had a serious not related TEAE.

None of the participants dosed with BNT162b2 experienced any severe local reactions while 6 participants (10%) dosed with BNT162b1 experienced severe systemic reactions. BNT162b1 was less well tolerated with every second participant experiencing severe systemic and local reactions on at least one occasion for the dose range 10, 20, 30, 50 and 60 µg groups. While the local tolerability profiles of BNT162b1 and BNT162b2 are, in general similar, the overall systemic reactogenicity profiles clearly are more favorable for BNT162b2 compared to BNT162b1.

Table 41: Overview of primary endpoint by age group

BNT162b1	Younger participants aged 18 to 55 years (N=84)	Older participants aged 56 to 85 years (N=36)
Any solicited local reaction n (%)	72 (86)	30 (83)
Any grade >= 3 local reaction n (%)	15 (18)	0 (0)
Any systemic reaction n (%)	77 (92)	33 (92)
Any grade >= 3 systemic reaction n (%)	37 (44)	10 (28)
Any TEAE n (%) E	38 (45) 83	13 (36) 24
Related TEAE n (%) E	30 (36) 51	5 (14) 9
Grade >= 3 TEAE n (%) E	2 (2) 4	4 (11) 4
Related grade >= 3 TEAE n (%) E	1 (1) 3	1 (3) 1
Any TESAE n (%) E	0 (0) 0	1 (3) 1
BNT162b2	**Younger participants aged 18 to 55 years (N=60)**	**Older participants aged 56 to 85 years (N=36)**
Any solicited local reaction n (%)	52 (87)	31 (86)
Any grade >= 3 local reaction n (%)	0 (0)	2 (6)
Any systemic reaction n (%)	53 (88)	26 (72)
Any grade >= 3 systemic reaction n (%)	6 (10)	4 (11)
Any TEAE n (%) E	26 (43) 51	12 (33) 20
Related TEAE n (%) E	6 (10) 9	2 (6) 4
Grade >=3 TEAE n (%) E	1 (2) 1	3 (8) 3
Related grade >=3 TEAE n (%) E	0 (0) 0	1 (3) 1
Any TESAE n (%) E	0 (0) 0	1 (3) 1

AE = adverse event; E = number of events; n = number of participants with the specified characteristic; N = total number of participants; SAF = Safety Set; TEAE = treatment-emergent adverse event; TESAE = treatment-emergent serious adverse event.
Source: Modified from Table 17 and Table 18.

Whereas no relevant change in routine clinical laboratory values occurred after IMP dosing, there were some transient increases in CRP and temporary reduction of blood lymphocyte counts observed in a dose-dependent manner. CRP is a well-known inflammatory serum protein previously described as biomarker for various infectious disease vaccines and an indicator of vaccine adjuvant activity (Tsai et al. 2005; Taylor et al. 2012; Doener et al. 2019; Destexhe et al. 2013). Based on previous clinical experience with RNA vaccines, the transient decrease in lymphocytes is likely attributable to innate immune stimulation-related redistribution of lymphocytes into lymphoid tissues (Kamphuis et al. 2006). Concomitant neutropenia was not observed. Both CRP levels and lymphocyte counts are considered pharmacodynamics markers for the mode-of-action of RNA vaccines.

13.2 Immunogenicity (antibody responses)

Participants dosed with BNT162b1 showed a strong dose-dependent antibody response. On Day 22, at 21 d after the first dose, virus neutralizing antibody GMTs had increased in a dose-dependent manner for the 1, 10, 30, and 50 µg dose groups. At 7 d after Dose 2

(Day 29), virus neutralizing GMTs showed a strong, dose level dependent booster response. In the 60 µg dose group, which was only dosed once, virus neutralizing GMTs remained at a lower level, indicating that a booster dose is necessary to increase functional antibody titers.

On Day 43 (21 d after Dose 2 of BNT162b1), virus neutralizing GMTs decreased (with exception of the 1 µg dose level). Day 43 virus neutralizing GMTs were 0.7-fold (1 µg) to 3.6-fold (50 µg) those of a COVID-19 HCS panel.

Participants dosed with BNT162b2 showed a strong IMP-induced antibody response. Virus neutralizing GMTs were detected at 21 d after Dose 1 (Day 22) and had increased substantially by 7 d after Dose 2 (Day 29) in participants aged 18 to 55 yrs (younger participants) dosed with ≥3 µg BNT162b2, and participants aged 56 to 85 yrs (older participants) dosed with 20 µg BNT162b2. Day 29 virus neutralizing GMTs were comparable between the two groups when dosed with 20 µg BNT162b2.

On Day 43 (21 d after Dose 2 of BNT162b2), virus neutralizing GMTs in the younger adult dose groups decreased for the 3, 20, and 30 µg dose groups. Thereafter, GMTs remained stable up to Day 85 (63 d after Dose 2) for younger adult dose groups 10, 20, and 30 µg BNT162b2 and were 1.3-fold to 1.9-fold those of a COVID-19 HCS panel.

All participants dosed with Dose 1 at ≥30 µg BNT162b1 or BNT162b2 seroconverted either by 7 d or 21 d after Dose 2 (Day 29 or Day 43). All participants dosed with 30 µg BNT162b2 remained seropositive throughout the follow-up until Day 85.

The observed kinetics of the BNT162b1- and BNT162b2-induced neutralizing antibody response is typical of antigen-activated B cells going through over proliferation, followed by rebound contraction with a gradual decline in numbers before stabilization of the immune response.

Walsh et al. (2020) reported similar serological responses elicited by BNT162b1 and BNT162b2 in the ongoing clinical study BNT162-02/C4591001 (ClinicalTrials.gov NCT04368728). For younger participants, the Day 29 virus neutralizing GMTs ranged from 2.8 to 3.8 times the GMT in the COVID-19 HCS panel. This is consistent with the data reported in this interim CSR, where Day 29 virus neutralizing GMTs for the 30 µg BNT162b1 and BNT162b2 dose groups were both 3.3-fold those of a COVID-19 HCS panel.

Both BNT162b1 and BNT162b2 elicited lower antigen-binding IgG GMCs and virus neutralizing GMTs in participants aged 65 to 85 yrs (elderly participants) compared to in participants aged 18 to 55 yrs (younger participants) in study BNT162-02/C4591001. The reported Day 29 (7 d after Dose 2) virus neutralizing GMTs in the elderly participants measured after dosing with 30 µg BNT162b1 or BNT162b2 still exceeded the GMT in the COVID-19 HCS panel by 1.1 to 1.6-fold. As observed with other vaccines this might be attributable to immunosenescence (Boraschi et al. 2010). However, comparable serological differences between the younger and older adults at Day 29 (n=12; 20 µg dose level) are shown in this interim CSR. Virus neutralizing GMTs were 2.1-fold compared to 2.2-fold those of a COVID-19 HCS panel.

In summary, the antibody responses elicited by BNT162b1 and BNT162b2 reported in this interim CSR largely complement and confirm the data reported by Mulligan et al. (2020) and Walsh et al. (2020) for the study BNT162-02/C4591001.

13.3 Cell-mediated immune responses

In both younger and older participants, two doses of BNT162b1 and BNT162b2 induced strong SARS-CoV-2 RBD-specific and S protein-specific T-cell responses. RBD- and S protein-specific $CD4^+$ T-cell responses were induced by BNT162b1 in 97.5% of participants and by BNT162b2 in 100% of participants. RBD- and S protein-specific $CD8^+$ T-cell responses were induced by BNT162b1 in 95.5% of participants and by BNT162b2 in 96.6% of participants.

The T-cell responses elicited by BNT162b2 were directed against additional epitopes of the S antigen outside RBD, indicating the induction of multi-epitopic responses by BNT162b2 in both age groups. The magnitude of the T-cell responses did not show clear dose dependency.

Dosing twice with BNT162b1 or BNT162b2, led to a substantial increase in incidence and magnitude of T-cell responses in both age groups, and across all dose levels for BNT162b1. While the magnitude of $CD4^+$ T-cell responses induced by BNT162b2 was also similar across different dose levels, the magnitude of $CD8^+$ T-cell responses was highest at the 30 µg dose level. The participants with the strongest $CD4^+$ T-cell responses had more than 10-fold of the memory responses observed in the same participants against immunodominant peptides from cytomegalovirus, Epstein-Barr virus, influenza virus, and tetanus toxoid. The same participants also had strong $CD8^+$ T-cell responses that were comparable to memory responses against the above mentioned viral antigens.

BNT162b2-induced $CD4^+$ and $CD8^+$ T-cell responses showed a decrease on Day 85, but remained detectable on Day 184 in almost all participants vaccinated with >10 µg at levels higher than or in range of recall antigen memory responses.

De novo induction of SARS-CoV-2 S or RBD protein directed T cells was confirmed using ICS. IFNγ-producing CD4 and CD8 T cells against SARS-CoV-2 S protein or RBD were induced robustly by both BNT162b1 and BNT162b2. No clear dose dependency was observed for both IMPs. The cytokine responses elicited after dosing with either BNT162b1 or BNT162b2 in older participants was mostly identical in response pattern and intensity with that in younger participants.

BNT162b1 and BNT162b2 induced poly-functional and pro-inflammatory $CD4^+$/$CD8^+$ T-cell responses in almost all participants. The detection of IFNγ, IL-2 but not IL-4 indicates a favorable Th1 profile and the absence of a potentially deleterious Th2 immune response.

BNT162b2 induced poly-functional and pro-inflammatory $CD4^+$/$CD8^+$ T-cell responses in almost all participants persisting in the majority of participants for up to 6 months after Dose 1. The Th1 polarization of the helper T-cell response was characterized by a robust IFNγ/IL-2 and only minor IL-4 production upon antigen-specific (wild-type SARS-CoV-2 S protein peptide pools) re-stimulation which was still observed, although with a reduced magnitude, at later time points.

This data complements the data reported by Mulligan et al. (2020) by providing a detailed characterization of antibody and T-cell immune responses elicited by dosing with BNT162b1.

13.4 Overall conclusions

- The majority of events reported were reactogenicity symptoms compared to TEAEs which were anticipated for IM-administered vaccines. The observed reactogenicity was mild or moderate in severity. The results of this study show that BNT162b1 and BNT162b2 are well tolerated and have an acceptable safety profile in younger participants aged 18 to 55 yrs and older participants aged 56 to 85 yrs.
- The frequency of local and systemic reactogenicity was generally lower for BNT162b2 compared to BNT162b1. BNT162b2 generally had a milder and therefore more favorable reactogenicity profile than BNT162b1 across dose levels.
- Participants dosed with BNT162b1 (1 to 50 µg) showed a strong, IMP- and dose-dependent antibody response in a SARS-CoV-2 neutralization assay by Day 22 (at 21 d after Dose 1). This response increased further by Day 29 (at 7 d after Dose 2), and the second dose elicited a booster effect. By Day 43 (21 d after Dose 2), the observed responses decreased for most dose levels. For participants dosed at ≥10 µg BNT162b1, Day 43 neutralizing GMTs were comparable or even superior to those of a COVID-19 HCS panel.
- Independent of age, participants dosed with BNT162b2 (1 to 30 µg) showed strong IMP-induced antibody responses. Virus neutralizing GMTs were detected after Dose 1 and showed a substantial booster response by 7 d after Dose 2 (Day 29) for dose level groups ≥3 µg. On Day 43, neutralizing GMTs in the younger participant dose groups decreased for the 3, 20, and 30 µg dose levels. Thereafter, GMTs remained stable up to Day 85 (63 d after Dose 2) for younger adult dose groups 10, 20, and 30 µg BNT162b2 and were comparable or even superior to those of a COVID-19 HCS panel.
- After dosing with ≥30 µg BNT162b1 and BNT162b2, all participants showed GMC- and GMT-based seroconversion by either 7 d or 21 d after Dose 2 (Day 29 or Day 43). All participants dosed with 30 µg BNT162b2 remained seropositive throughout the follow-up until Day 85.
- The observed kinetics of the BNT162b1 and BNT162b2 induced neutralizing antibody response is typical of antigen-activated B cells going through over proliferation, followed by rebound contraction with a gradual decline in numbers before stabilization of the immune response.
- In both younger and older participants, two doses of BNT162b1 and BNT162b2 induced strong SARS-CoV-2 RBD-specific and S protein-specific T-cell responses. RBD- and S protein-specific $CD4^+$ T-cell responses were induced by BNT162b1 in 97.5% of participants and by BNT162b2 in 100% of participants. RBD- and S protein-specific $CD8^+$ T-cell responses were induced by BNT162b1 in 95.5% of participants and by BNT162b2 in 96.6% of participants. The magnitude of the T-cell responses did not show clear dose dependency.

- BNT162b2-induced $CD4^+$ and $CD8^+$ T-cell responses showed a decrease on Day 85, but remained detectable on Day 184 in almost all participants vaccinated with >10 µg at levels higher than or in range of recall antigen memory responses.
- BNT162b1 and BNT162b2 induced poly-functional and pro-inflammatory $CD4^+$/$CD8^+$ T-cell responses in almost all participants. The detection of IFNγ and IL-2, but no or only minor IL-4 production, indicates a favorable Th1 profile. No notable age-related differences were observed.
- For the majority of participants, the strong S-specific IFNγ^+ and IL-2^+CD8^+ and Th1 $CD4^+$ T-cell responses contracted by Day 43 (21 d post-Dose 2) and plateaued at a lower level towards Day 85 (63 d post-Dose 2). This observation held true for all dose groups analyzed with varying response magnitudes between individuals. For the younger participants, the cell-mediated immune responses remained detectable until Day 184 (162 d post-Dose 2).
- The favorable tolerability profile was the major driver for choosing BNT162b2 for further study in the Phase II/III evaluation of efficacy.

14 TABLES AND FIGURES

Note to reader

BNT162b1

General considerations

14.1 Disposition and baseline characteristics

Table 14.1-2-1: Analysis sets - BNT162b1

14.1-3 Premature discontinuation

Table 14.1-3.1-1: Premature discontinuation by group - BNT162b1

14.1-4 Demographic characteristics

Table 14.1-4.1-1: Demographic characteristics, continuous - BNT162b1

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14.3 Safety

14.3.1 Primary endpoints

14.3.1-1 Local reactions

Table 14.3.1-1.1-1: Summary of solicited local reactions - BNT162b1

Table 14.3.1-1.2-1: Summary of solicited local reactions - completers only - BNT162b1

Table 14.3.1-1.3-1: Frequency of subjects with solicited local reactions by grade - BNT162b1

Table 14.3.1-1.4-1: Frequency of subjects with solicited local reactions by grade - completers only - BNT162b1

Table 14.3.1-1.5.1-1: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b1

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Table 14.3.1-1.6.1-1: Frequency of subjects with solicited local and any solicited reactions per day - BNT162b1

Table 14.3.1-1.6.2-1: Frequency of subjects with solicited local reactions by term per day - BNT162b1

14.3.1-2 Systemic reactions

Table 14.3.1-2.1-1: Summary of solicited systemic reactions - BNT162b1

Table 14.3.1-2.2-1: Summary of solicited systemic reactions - completers only - BNT162b1

Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

BNT162b2

15 REFERENCES

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16 APPENDICES

16.1 Study information

16.1.1 Protocol and protocol amendments

16.1.1.1 Protocol incl. amendments 01 to 06

Clinical study protocol incl. amendments 01 to 06

16.1.1.2 Informed consent forms

Participant information leaflet and declaration of consent

Participant information leaflet and declaration of consent – Additional blood sampling: Immunomonitoring

Participant information leaflet and declaration of consent – Additional blood sampling: Pharmacogenomic testing HLA

16.1.1.3 Protocol amendment history incl. amendments 01 to 06

Clinical study protocol amendment history including amendments 01 to 06

16.1.1.4 Manuals

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Laboratory manual

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16.1.2 Sample case report form

Sample case report form

16.1.3 List of IECs

16.1.4 List of investigators and description of investigators and other important participants contributing to the study

16.1.4.1 List of investigators

16.1.4.2 Brief curriculum vita for all investigators and other important participants

Curriculum vitae Baumann

Curriculum vitae Berse

Curriculum vitae Casjens

Curriculum vitae Schultz

Curriculum vitae Seitz

16.1.4.3 List of providers

16.1.5 Signatures of coordinating investigator and sponsor signatories

Coordinating investigator’s signature

Sponsor signatures

Participant data listings - Notes for the reader

To harmonize data reporting across the different BNT162 clinical studies, the following terminology was harmonized in this interim clinical study report (CSR). The protocol, Statistical Analysis Plan (SAP), and the CSR Section 14 tables/figures, and the Section 16 listings use the original BioNTech terminology:

BioNTech terminology in the protocol, SAP and the CSR appendices	Harmonized terminology used in the interim CSR
Boost (dose)	Dose 2
Cohort	Dose group
Immunization	Dosing
Immunized	Dosed
Prime (dose)	Dose 1
(Trial) Subject	Participant
Trial	Study
Vaccinated	Dosed
Vaccination	Dosing
Vaccine	Investigational medicinal product

General considerations

General details:

The programming is based on SAP final version 4.0.

The last digit of the numbering of tables, figures and listings indicates the vaccine: 1 for BNT162b1, 2 for BNT162a1, 3 for BNT162b2, 4 for BNT162c2 (single dose) and 5 for BNT162c2 (prime/boost).

Some tables presenting adverse events are presented twice: once using the safety set and once using the safety boost set.

The adverse events based on solicited reporting via subjects diaries are defined in the file BNT162-01_AEs_based_on_solicited_reporting_via_subjects_diaries_v2.0 MBx_SSt.

The SDTM data used was received on 03NOV2020 in the folder SDTM_Group_BC_cutoff_20201023.

The adverse events intensity was assessed on different scales:
- the 1 µg, 10 µg, 30 µg, 50 µg and 60 µg young cohorts was assessed on a 3-point scale (mild, moderate, severe)
- the 3 µg and 20 µg young cohorts as well as the older cohorts were assessed on a 4-point scale (mild, moderate, severe, potentially life-threatening).

Programming details:

If a table which presents categories has any all zero rows, these rows are suppressed.

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14.1 Disposition and baseline characteristics

Table 14.1-2-1: Analysis sets - BNT162b1

Safety set

	Younger dose ranging cohorts							
	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Safety set (SAF)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
Safety boost set (SAFB)	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	0 (0)	69 (82)
Prime + 7 Days completers set (CP7)	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	83 (99)
Prime to Boost or Prime + 28 Days completers set (CPBP28)	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	81 (96)
Boost + 7 Days completers set (CB7)	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	0 (0)	69 (82)
Boost + 28 Days completers set (CB28)	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	0 (0)	69 (82)
Prime or Boost + 28 Days completers set (CPB28)	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	81 (96)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tbase_Disp_2.sas (Page 1 of 2)

Table 14.1-2-1: Analysis sets - BNT162b1

Safety set

	Older dose ranging cohorts				
	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Safety set (SAF)	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
Safety boost set (SAFB)	12 (100)	11 (92)	12 (100)	35 (97)	104 (87)
Prime + 7 Days completers set (CP7)	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)
Prime to Boost or Prime + 28 Days completers set (CPBP28)	12 (100)	12 (100)	12 (100)	36 (100)	117 (98)
Boost + 7 Days completers set (CB7)	12 (100)	11 (92)	12 (100)	35 (97)	104 (87)
Boost + 28 Days completers set (CB28)	12 (100)	0 (0)	0 (0)	12 (33)	81 (68)
Prime or Boost + 28 Days completers set (CPB28)	12 (100)	1 (8)	0 (0)	13 (36)	94 (78)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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14.1-3 Premature discontinuation

Table 14.1-3.1-1: Premature discontinuation by group - BNT162b1

Safety set

		Younger dose ranging cohorts							
		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Reason for premature treatment discontinuation	Any	0 (0)	0 (0)	1 (8)	2 (17)	0 (0)	1 (8)	0 (0)	4 (5)
	Other	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	2 (2)
	Adverse Event	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Withdrawal By Subject	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.1-3.1-1: Premature discontinuation by group - BNT162b1

Safety set

		Older dose ranging cohorts				
		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Reason for premature treatment discontinuation	Any	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
	Other	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Adverse Event	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Withdrawal By Subject	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tbase_Disp_3_2.sas (Page 2 of 2)

14.1-4 Demographic characteristics

Table 14.1-4.1-1: Demographic characteristics, continuous - BNT162b1

Safety set

		Younger dose ranging cohorts							
		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Age [years]	n	12	12	12	12	12	12	12	84
	Mean (SD)	38.21 (10.48)	41.44 (11.27)	43.62 (11.03)	39.42 (11.41)	35.74 (8.60)	33.88 (10.72)	35.81 (12.50)	38.30 (10.99)
	Min	21.4	23.8	25.1	20.9	23.9	19.9	20.9	19.9
	Median	39.83	45.00	46.58	37.50	35.17	30.79	30.13	36.29
	Max	55.8	55.2	55.0	55.8	54.0	47.8	53.2	55.8
Height [cm]	n	12	12	12	12	12	12	12	84
	Mean (SD)	169.5 (8.8)	175.2 (7.9)	171.1 (9.7)	173.5 (10.0)	176.1 (9.0)	173.1 (7.8)	176.4 (9.6)	173.5 (9.0)
	Min	152	164	155	159	162	159	162	152
	Median	169.0	174.0	171.0	171.0	176.5	173.5	178.0	172.0
	Max	183	194	193	192	189	185	192	194
Weight [kg]	n	12	12	12	12	12	12	12	84
	Mean (SD)	72.99 (14.79)	77.11 (14.07)	71.57 (14.09)	73.58 (11.88)	79.84 (13.81)	76.73 (13.32)	78.70 (13.85)	75.79 (13.52)
	Min	50.1	57.6	54.5	55.1	59.0	57.4	62.2	50.1
	Median	70.25	77.65	71.50	72.55	79.40	79.40	77.15	75.45
	Max	97.0	110.2	100.5	103.7	97.0	97.0	105.6	110.2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation.

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Table 14.1-4.1-1: Demographic characteristics, continuous - BNT162b1

Safety set

		Younger dose ranging cohorts							
		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
BMI [kg/m2]	n	12	12	12	12	12	12	12	84
	Mean (SD)	25.17 (2.89)	24.94 (2.68)	24.20 (2.32)	24.34 (2.33)	25.68 (3.44)	25.52 (3.50)	25.19 (3.09)	25.00 (2.87)
	Min	21.2	20.9	21.0	20.6	20.2	19.6	19.8	19.6
	Median	25.35	25.05	23.95	24.05	26.15	25.20	25.15	25.00
	Max	29.6	29.3	28.7	28.1	29.8	29.9	29.8	29.9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation.

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Table 14.1-4.1-1: Demographic characteristics, continuous - BNT162b1

Safety set

		Older dose ranging cohorts				
		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Age [years]	n	12	12	12	36	120
	Mean (SD)	64.31 (5.89)	65.66 (5.95)	67.16 (6.47)	65.71 (6.05)	46.53 (15.94)
	Min	56.1	57.0	57.3	56.1	19.9
	Median	64.17	67.38	67.96	67.21	47.63
	Max	73.9	75.8	76.8	76.8	76.8
Height [cm]	n	12	12	12	36	120
	Mean (SD)	170.2 (9.1)	165.7 (7.5)	165.3 (8.6)	167.0 (8.5)	171.6 (9.3)
	Min	156	153	155	153	152
	Median	169.5	165.5	162.0	166.5	171.0
	Max	190	178	179	190	194
Weight [kg]	n	12	12	12	36	120
	Mean (SD)	71.90 (10.98)	70.38 (9.14)	69.98 (8.06)	70.75 (9.23)	74.28 (12.57)
	Min	55.6	57.6	60.3	55.6	50.1
	Median	74.90	68.85	68.10	69.00	72.55
	Max	91.7	87.2	87.1	91.7	110.2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation.

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Table 14.1-4.1-1: Demographic characteristics, continuous - BNT162b1

Safety set

		Older dose ranging cohorts				
		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
BMI [kg/m2]	n	12	12	12	36	120
	Mean (SD)	24.73 (2.46)	25.59 (2.22)	25.63 (2.22)	25.32 (2.28)	25.10 (2.70)
	Min	20.7	22.8	22.5	20.7	19.6
	Median	25.50	24.95	25.65	25.40	25.00
	Max	27.4	28.5	28.6	28.6	29.9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation.

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Table 14.1-4.2-1: Demographic characteristics, categorical - BNT162b1

Safety set

		Younger dose ranging cohorts							
		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Gender	Male	5 (42)	6 (50)	4 (33)	8 (67)	8 (67)	6 (50)	7 (58)	44 (52)
	Female	7 (58)	6 (50)	8 (67)	4 (33)	4 (33)	6 (50)	5 (42)	40 (48)
Ethnicity	Hispanic or Latino	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
	Not Hispanic or Latino	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	82 (98)
Race	Asian	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (2)
	Black or African American	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	White	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	12 (100)	11 (92)	81 (96)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.1-4.2-1: Demographic characteristics, categorical - BNT162b1

Safety set

		Older dose ranging cohorts				
		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Gender	Male	7 (58)	2 (17)	4 (33)	13 (36)	57 (48)
	Female	5 (42)	10 (83)	8 (67)	23 (64)	63 (53)
Ethnicity	Hispanic or Latino	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Not Hispanic or Latino	12 (100)	12 (100)	12 (100)	36 (100)	118 (98)
Race	Asian	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Black or African American	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	White	12 (100)	12 (100)	12 (100)	36 (100)	117 (98)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tbase_Demo_4_2.sas (Page 2 of 2)

14.3 Safety
14.3.1 Primary endpoints

14.3.1-1 Local reactions

Table 14.3.1-1.1-1: Summary of solicited local reactions - BNT162b1

Safety set

		Younger dose ranging cohorts							
Time interval		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Prime up to Day 7 after prime	nn	12	12	12	12	12	12	12	84
	Any local reaction n (%)	6 (50)	5 (42)	10 (83)	12 (100)	11 (92)	12 (100)	12 (100)	68 (81)
	Any grade >= 3 local reaction n (%)	0 (0)	0 (0)	1 (8)	2 (17)	4 (33)	2 (17)	1 (8)	10 (12)
Boost up to Day 7 after boost	nn	12	12	11	11	12	11	N/A	69
	Any local reaction n (%)	7 (58)	5 (42)	10 (91)	11 (100)	11 (92)	11 (100)	N/A	55 (80)
	Any grade >= 3 local reaction n (%)	2 (17)	0 (0)	0 (0)	0 (0)	2 (17)	3 (27)	N/A	7 (10)
Combined interval	nn	12	12	12	12	12	12	12	84
	Any local reaction n (%)	7 (58)	6 (50)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	72 (86)
	Any grade >= 3 local reaction n (%)	2 (17)	0 (0)	1 (8)	2 (17)	5 (42)	4 (33)	1 (8)	15 (18)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reactions; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-1.1-1: Summary of solicited local reactions - BNT162b1

Safety set

		Older dose ranging cohorts				
Time interval		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Prime up to Day 7 after prime	nn	12	12	12	36	120
	Any local reaction n (%)	7 (58)	11 (92)	11 (92)	29 (81)	97 (81)
	Any grade >= 3 local reaction n (%)	0 (0)	0 (0)	0 (0)	0 (0)	10 (8)
Boost up to Day 7 after boost	nn	12	11	12	35	104
	Any local reaction n (%)	8 (67)	9 (82)	9 (75)	26 (74)	81 (78)
	Any grade >= 3 local reaction n (%)	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
Combined interval	nn	12	12	12	36	120
	Any local reaction n (%)	8 (67)	11 (92)	11 (92)	30 (83)	102 (85)
	Any grade >= 3 local reaction n (%)	0 (0)	0 (0)	0 (0)	0 (0)	15 (13)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reactions; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

Program: Tsaf_locR_1-2.sas (Page 2 of 2)

Table 14.3.1-1.2-1: Summary of solicited local reactions - completers only - BNT162b1

Safety set

		Younger dose ranging cohorts							
Time interval		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=11)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=83)
Prime up to Day 7 after prime	nn	12	12	12	11	12	12	12	83
	Any local reaction n (%)	6 (50)	5 (42)	10 (83)	11 (100)	11 (92)	12 (100)	12 (100)	67 (81)
	Any grade >= 3 local reaction n (%)	0 (0)	0 (0)	1 (8)	2 (18)	4 (33)	2 (17)	1 (8)	10 (12)
Boost up to Day 7 after boost	nn	12	12	11	11	12	11	N/A	69
	Any local reaction n (%)	7 (58)	5 (42)	10 (91)	11 (100)	11 (92)	11 (100)	N/A	55 (80)
	Any grade >= 3 local reaction n (%)	2 (17)	0 (0)	0 (0)	0 (0)	2 (17)	3 (27)	N/A	7 (10)
Combined interval	nn	12	12	11	11	12	11	N/A	69
	Any local reaction n (%)	7 (58)	6 (50)	10 (91)	11 (100)	12 (100)	11 (100)	N/A	57 (83)
	Any grade >= 3 local reaction n (%)	2 (17)	0 (0)	0 (0)	2 (18)	5 (42)	4 (36)	N/A	13 (19)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reactions; nn = number of subjects with any information on local reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

Program: Tsaf_locR_1-2.sas (Page 1 of 2)

Table 14.3.1-1.2-1: Summary of solicited local reactions - completers only - BNT162b1

Safety set

		Older dose ranging cohorts				
Time interval		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=119)
Prime up to Day 7 after prime	nn	12	12	12	36	119
	Any local reaction n (%)	7 (58)	11 (92)	11 (92)	29 (81)	96 (81)
	Any grade >= 3 local reaction n (%)	0 (0)	0 (0)	0 (0)	0 (0)	10 (8)
Boost up to Day 7 after boost	nn	12	11	12	35	104
	Any local reaction n (%)	8 (67)	9 (82)	9 (75)	26 (74)	81 (78)
	Any grade >= 3 local reaction n (%)	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
Combined interval	nn	12	11	12	35	104
	Any local reaction n (%)	8 (67)	10 (91)	11 (92)	29 (83)	86 (83)
	Any grade >= 3 local reaction n (%)	0 (0)	0 (0)	0 (0)	0 (0)	13 (13)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reactions; nn = number of subjects with any information on local reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-1.3-1: Frequency of subjects with solicited local reactions by grade - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Prime up to Day 7 after prime		nn	12	12	12	12	12	12	12	84
	Any	Any n (%)	6 (50)	5 (42)	10 (83)	12 (100)	11 (92)	12 (100)	12 (100)	68 (81)
		Mild n (%)	6 (50)	5 (42)	8 (67)	12 (100)	11 (92)	12 (100)	12 (100)	66 (79)
		Moderate n (%)	2 (17)	1 (8)	4 (33)	4 (33)	5 (42)	7 (58)	7 (58)	30 (36)
		Severe n (%)	0 (0)	0 (0)	1 (8)	2 (17)	4 (33)	2 (17)	1 (8)	10 (12)
	Pain	Any n (%)	4 (33)	3 (25)	6 (50)	11 (92)	10 (83)	11 (92)	12 (100)	57 (68)
		Mild n (%)	4 (33)	3 (25)	6 (50)	11 (92)	10 (83)	9 (75)	12 (100)	55 (65)
		Moderate n (%)	0 (0)	1 (8)	1 (8)	4 (33)	0 (0)	4 (33)	2 (17)	12 (14)
		Severe n (%)	0 (0)	0 (0)	1 (8)	2 (17)	3 (25)	2 (17)	1 (8)	9 (11)
	Tenderness	Any n (%)	6 (50)	5 (42)	10 (83)	11 (92)	11 (92)	12 (100)	11 (92)	66 (79)
		Mild n (%)	4 (33)	5 (42)	8 (67)	11 (92)	10 (83)	10 (83)	11 (92)	59 (70)
		Moderate n (%)	2 (17)	1 (8)	4 (33)	3 (25)	5 (42)	7 (58)	7 (58)	29 (35)
		Severe n (%)	0 (0)	0 (0)	1 (8)	1 (8)	3 (25)	1 (8)	0 (0)	6 (7)
	Erythema/Redness	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	3 (25)	0 (0)	6 (7)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-1.3-1: Frequency of subjects with solicited local reactions by grade - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Prime up to Day 7 after prime	Erythema/Redness	Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	3 (25)	0 (0)	6 (7)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	0 (0)	3 (4)
	Induration/Swelling	Any n (%)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	3 (25)	1 (8)	7 (8)
		Mild n (%)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	2 (17)	1 (8)	6 (7)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
Boost up to Day 7 after boost		nn	12	12	11	11	12	11	N/A	69
	Any	Any n (%)	7 (58)	5 (42)	10 (91)	11 (100)	11 (92)	11 (100)	N/A	55 (80)
		Mild n (%)	5 (42)	5 (42)	10 (91)	10 (91)	10 (83)	11 (100)	N/A	51 (74)
		Moderate n (%)	3 (25)	1 (8)	1 (9)	4 (36)	10 (83)	7 (64)	N/A	26 (38)
		Severe n (%)	2 (17)	0 (0)	0 (0)	0 (0)	2 (17)	3 (27)	N/A	7 (10)
	Pain	Any n (%)	6 (50)	3 (25)	7 (64)	8 (73)	11 (92)	11 (100)	N/A	46 (67)
		Mild n (%)	4 (33)	3 (25)	7 (64)	7 (64)	9 (75)	10 (91)	N/A	40 (58)
		Moderate n (%)	3 (25)	1 (8)	1 (9)	3 (27)	9 (75)	6 (55)	N/A	23 (33)
		Severe n (%)	1 (8)	0 (0)	0 (0)	0 (0)	2 (17)	2 (18)	N/A	5 (7)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-1.3-1: Frequency of subjects with solicited local reactions by grade - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Boost up to Day 7 after boost	Tenderness	Any n (%)	6 (50)	5 (42)	9 (82)	11 (100)	10 (83)	11 (100)	N/A	52 (75)
		Mild n (%)	3 (25)	5 (42)	9 (82)	10 (91)	9 (75)	10 (91)	N/A	46 (67)
		Moderate n (%)	3 (25)	1 (8)	1 (9)	3 (27)	10 (83)	6 (55)	N/A	24 (35)
		Severe n (%)	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	2 (18)	N/A	5 (7)
	Erythema/Redness	Any n (%)	0 (0)	1 (8)	0 (0)	1 (9)	0 (0)	1 (9)	N/A	3 (4)
		Mild n (%)	0 (0)	1 (8)	0 (0)	1 (9)	0 (0)	1 (9)	N/A	3 (4)
	Induration/Swelling	Any n (%)	2 (17)	1 (8)	1 (9)	1 (9)	0 (0)	1 (9)	N/A	6 (9)
		Mild n (%)	0 (0)	1 (8)	1 (9)	1 (9)	0 (0)	1 (9)	N/A	4 (6)
		Moderate n (%)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	2 (3)
Combined interval		nn	12	12	12	12	12	12	12	84
	Any	Any n (%)	7 (58)	6 (50)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	72 (86)
		Mild n (%)	7 (58)	6 (50)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	72 (86)
		Moderate n (%)	5 (42)	1 (8)	5 (42)	6 (50)	11 (92)	10 (83)	7 (58)	45 (54)
		Severe n (%)	2 (17)	0 (0)	1 (8)	2 (17)	5 (42)	4 (33)	1 (8)	15 (18)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-1.3-1: Frequency of subjects with solicited local reactions by grade - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Combined interval	Pain	Any n (%)	6 (50)	4 (33)	9 (75)	12 (100)	12 (100)	12 (100)	12 (100)	67 (80)
		Mild n (%)	5 (42)	4 (33)	9 (75)	12 (100)	12 (100)	11 (92)	12 (100)	65 (77)
		Moderate n (%)	3 (25)	1 (8)	2 (17)	5 (42)	9 (75)	8 (67)	2 (17)	30 (36)
		Severe n (%)	1 (8)	0 (0)	1 (8)	2 (17)	4 (33)	3 (25)	1 (8)	12 (14)
	Tenderness	Any n (%)	7 (58)	6 (50)	11 (92)	12 (100)	11 (92)	12 (100)	11 (92)	70 (83)
		Mild n (%)	6 (50)	6 (50)	10 (83)	12 (100)	10 (83)	12 (100)	11 (92)	67 (80)
		Moderate n (%)	5 (42)	1 (8)	5 (42)	6 (50)	11 (92)	10 (83)	7 (58)	45 (54)
		Severe n (%)	2 (17)	0 (0)	1 (8)	1 (8)	4 (33)	3 (25)	0 (0)	11 (13)
	Erythema/Redness	Any n (%)	0 (0)	1 (8)	0 (0)	1 (8)	3 (25)	3 (25)	0 (0)	8 (10)
		Mild n (%)	0 (0)	1 (8)	0 (0)	1 (8)	3 (25)	3 (25)	0 (0)	8 (10)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	0 (0)	3 (4)
	Induration/Swelling	Any n (%)	2 (17)	1 (8)	1 (8)	2 (17)	2 (17)	4 (33)	1 (8)	13 (15)
		Mild n (%)	0 (0)	1 (8)	1 (8)	2 (17)	2 (17)	3 (25)	1 (8)	10 (12)
		Moderate n (%)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

Program: Tsaf_locR_3-4.sas (Page 4 of 8)

Table 14.3.1-1.3-1: Frequency of subjects with solicited local reactions by grade - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Prime up to Day 7 after prime		nn	12	12	12	36	120
	Any	Any n (%)	7 (58)	11 (92)	11 (92)	29 (81)	97 (81)
		Mild n (%)	7 (58)	10 (83)	10 (83)	27 (75)	93 (78)
		Moderate n (%)	0 (0)	4 (33)	3 (25)	7 (19)	37 (31)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	10 (8)
	Pain	Any n (%)	6 (50)	7 (58)	9 (75)	22 (61)	79 (66)
		Mild n (%)	6 (50)	7 (58)	9 (75)	22 (61)	77 (64)
		Moderate n (%)	0 (0)	1 (8)	1 (8)	2 (6)	14 (12)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	9 (8)
	Tenderness	Any n (%)	7 (58)	10 (83)	10 (83)	27 (75)	93 (78)
		Mild n (%)	7 (58)	8 (67)	9 (75)	24 (67)	83 (69)
		Moderate n (%)	0 (0)	4 (33)	3 (25)	7 (19)	36 (30)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
	Erythema/Redness	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-1.3-1: Frequency of subjects with solicited local reactions by grade - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Prime up to Day 7 after prime	Erythema/Redness	Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Induration/Swelling	Any n (%)	0 (0)	2 (17)	1 (8)	3 (8)	10 (8)
		Mild n (%)	0 (0)	2 (17)	1 (8)	3 (8)	9 (8)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Boost up to Day 7 after boost		nn	12	11	12	35	104
	Any	Any n (%)	8 (67)	9 (82)	9 (75)	26 (74)	81 (78)
		Mild n (%)	8 (67)	9 (82)	8 (67)	25 (71)	76 (73)
		Moderate n (%)	3 (25)	3 (27)	6 (50)	12 (34)	38 (37)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
	Pain	Any n (%)	6 (50)	8 (73)	8 (67)	22 (63)	68 (65)
		Mild n (%)	6 (50)	8 (73)	7 (58)	21 (60)	61 (59)
		Moderate n (%)	2 (17)	1 (9)	4 (33)	7 (20)	30 (29)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-1.3-1: Frequency of subjects with solicited local reactions by grade - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Boost up to Day 7 after boost	Tenderness	Any n (%)	8 (67)	8 (73)	9 (75)	25 (71)	77 (74)
		Mild n (%)	8 (67)	8 (73)	8 (67)	24 (69)	70 (67)
		Moderate n (%)	2 (17)	3 (27)	6 (50)	11 (31)	35 (34)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
	Erythema/Redness	Any n (%)	2 (17)	0 (0)	2 (17)	4 (11)	7 (7)
		Mild n (%)	2 (17)	0 (0)	2 (17)	4 (11)	7 (7)
	Induration/Swelling	Any n (%)	2 (17)	3 (27)	2 (17)	7 (20)	13 (13)
		Mild n (%)	2 (17)	3 (27)	2 (17)	7 (20)	11 (11)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Combined interval		nn	12	12	12	36	120
	Any	Any n (%)	8 (67)	11 (92)	11 (92)	30 (83)	102 (85)
		Mild n (%)	8 (67)	11 (92)	11 (92)	30 (83)	102 (85)
		Moderate n (%)	3 (25)	5 (42)	7 (58)	15 (42)	60 (50)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	15 (13)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-1.3-1: Frequency of subjects with solicited local reactions by grade - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Combined interval	Pain	Any n (%)	7 (58)	10 (83)	10 (83)	27 (75)	94 (78)
		Mild n (%)	7 (58)	10 (83)	10 (83)	27 (75)	92 (77)
		Moderate n (%)	2 (17)	2 (17)	5 (42)	9 (25)	39 (33)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	12 (10)
	Tenderness	Any n (%)	8 (67)	10 (83)	10 (83)	28 (78)	98 (82)
		Mild n (%)	8 (67)	10 (83)	10 (83)	28 (78)	95 (79)
		Moderate n (%)	2 (17)	5 (42)	7 (58)	14 (39)	59 (49)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	11 (9)
	Erythema/Redness	Any n (%)	2 (17)	0 (0)	2 (17)	4 (11)	12 (10)
		Mild n (%)	2 (17)	0 (0)	2 (17)	4 (11)	12 (10)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Induration/Swelling	Any n (%)	2 (17)	3 (25)	3 (25)	8 (22)	21 (18)
		Mild n (%)	2 (17)	3 (25)	3 (25)	8 (22)	18 (15)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-1.4-1: Frequency of subjects with solicited local reactions by grade - completers only - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=11)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=83)
Prime up to Day 7 after prime		nn	12	12	12	11	12	12	12	83
	Any	Any n (%)	6 (50)	5 (42)	10 (83)	11 (100)	11 (92)	12 (100)	12 (100)	67 (81)
		Mild n (%)	6 (50)	5 (42)	8 (67)	11 (100)	11 (92)	12 (100)	12 (100)	65 (78)
		Moderate n (%)	2 (17)	1 (8)	4 (33)	4 (36)	5 (42)	7 (58)	7 (58)	30 (36)
		Severe n (%)	0 (0)	0 (0)	1 (8)	2 (18)	4 (33)	2 (17)	1 (8)	10 (12)
	Pain	Any n (%)	4 (33)	3 (25)	6 (50)	10 (91)	10 (83)	11 (92)	12 (100)	56 (67)
		Mild n (%)	4 (33)	3 (25)	6 (50)	10 (91)	10 (83)	9 (75)	12 (100)	54 (65)
		Moderate n (%)	0 (0)	1 (8)	1 (8)	4 (36)	0 (0)	4 (33)	2 (17)	12 (14)
		Severe n (%)	0 (0)	0 (0)	1 (8)	2 (18)	3 (25)	2 (17)	1 (8)	9 (11)
	Tenderness	Any n (%)	6 (50)	5 (42)	10 (83)	10 (91)	11 (92)	12 (100)	11 (92)	65 (78)
		Mild n (%)	4 (33)	5 (42)	8 (67)	10 (91)	10 (83)	10 (83)	11 (92)	58 (70)
		Moderate n (%)	2 (17)	1 (8)	4 (33)	3 (27)	5 (42)	7 (58)	7 (58)	29 (35)
		Severe n (%)	0 (0)	0 (0)	1 (8)	1 (9)	3 (25)	1 (8)	0 (0)	6 (7)
	Erythema/Redness	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	3 (25)	0 (0)	6 (7)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-1.4-1: Frequency of subjects with solicited local reactions by grade - completers only - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=11)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=83)
Prime up to Day 7 after prime	Erythema/Redness	Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	3 (25)	0 (0)	6 (7)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	0 (0)	3 (4)
	Induration/Swelling	Any n (%)	0 (0)	0 (0)	0 (0)	1 (9)	2 (17)	3 (25)	1 (8)	7 (8)
		Mild n (%)	0 (0)	0 (0)	0 (0)	1 (9)	2 (17)	2 (17)	1 (8)	6 (7)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
Boost up to Day 7 after boost		nn	12	12	11	11	12	11	N/A	69
	Any	Any n (%)	7 (58)	5 (42)	10 (91)	11 (100)	11 (92)	11 (100)	N/A	55 (80)
		Mild n (%)	5 (42)	5 (42)	10 (91)	10 (91)	10 (83)	11 (100)	N/A	51 (74)
		Moderate n (%)	3 (25)	1 (8)	1 (9)	4 (36)	10 (83)	7 (64)	N/A	26 (38)
		Severe n (%)	2 (17)	0 (0)	0 (0)	0 (0)	2 (17)	3 (27)	N/A	7 (10)
	Pain	Any n (%)	6 (50)	3 (25)	7 (64)	8 (73)	11 (92)	11 (100)	N/A	46 (67)
		Mild n (%)	4 (33)	3 (25)	7 (64)	7 (64)	9 (75)	10 (91)	N/A	40 (58)
		Moderate n (%)	3 (25)	1 (8)	1 (9)	3 (27)	9 (75)	6 (55)	N/A	23 (33)
		Severe n (%)	1 (8)	0 (0)	0 (0)	0 (0)	2 (17)	2 (18)	N/A	5 (7)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-1.4-1: Frequency of subjects with solicited local reactions by grade - completers only - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=11)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=83)
Boost up to Day 7 after boost	Tenderness	Any n (%)	6 (50)	5 (42)	9 (82)	11 (100)	10 (83)	11 (100)	N/A	52 (75)
		Mild n (%)	3 (25)	5 (42)	9 (82)	10 (91)	9 (75)	10 (91)	N/A	46 (67)
		Moderate n (%)	3 (25)	1 (8)	1 (9)	3 (27)	10 (83)	6 (55)	N/A	24 (35)
		Severe n (%)	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	2 (18)	N/A	5 (7)
	Erythema/Redness	Any n (%)	0 (0)	1 (8)	0 (0)	1 (9)	0 (0)	1 (9)	N/A	3 (4)
		Mild n (%)	0 (0)	1 (8)	0 (0)	1 (9)	0 (0)	1 (9)	N/A	3 (4)
	Induration/Swelling	Any n (%)	2 (17)	1 (8)	1 (9)	1 (9)	0 (0)	1 (9)	N/A	6 (9)
		Mild n (%)	0 (0)	1 (8)	1 (9)	1 (9)	0 (0)	1 (9)	N/A	4 (6)
		Moderate n (%)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	2 (3)
Combined interval		nn	12	12	11	11	12	11	N/A	69
	Any	Any n (%)	7 (58)	6 (50)	10 (91)	11 (100)	12 (100)	11 (100)	N/A	57 (83)
		Mild n (%)	7 (58)	6 (50)	10 (91)	11 (100)	12 (100)	11 (100)	N/A	57 (83)
		Moderate n (%)	5 (42)	1 (8)	4 (36)	6 (55)	11 (92)	9 (82)	N/A	36 (52)
		Severe n (%)	2 (17)	0 (0)	0 (0)	2 (18)	5 (42)	4 (36)	N/A	13 (19)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-1.4-1: Frequency of subjects with solicited local reactions by grade - completers only - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=11)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=83)
Combined interval	Pain	Any n (%)	6 (50)	4 (33)	8 (73)	11 (100)	12 (100)	11 (100)	N/A	52 (75)
		Mild n (%)	5 (42)	4 (33)	8 (73)	11 (100)	12 (100)	10 (91)	N/A	50 (72)
		Moderate n (%)	3 (25)	1 (8)	1 (9)	5 (45)	9 (75)	7 (64)	N/A	26 (38)
		Severe n (%)	1 (8)	0 (0)	0 (0)	2 (18)	4 (33)	3 (27)	N/A	10 (14)
	Tenderness	Any n (%)	7 (58)	6 (50)	10 (91)	11 (100)	11 (92)	11 (100)	N/A	56 (81)
		Mild n (%)	6 (50)	6 (50)	9 (82)	11 (100)	10 (83)	11 (100)	N/A	53 (77)
		Moderate n (%)	5 (42)	1 (8)	4 (36)	6 (55)	11 (92)	9 (82)	N/A	36 (52)
		Severe n (%)	2 (17)	0 (0)	0 (0)	1 (9)	4 (33)	3 (27)	N/A	10 (14)
	Erythema/Redness	Any n (%)	0 (0)	1 (8)	0 (0)	1 (9)	3 (25)	2 (18)	N/A	7 (10)
		Mild n (%)	0 (0)	1 (8)	0 (0)	1 (9)	3 (25)	2 (18)	N/A	7 (10)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	N/A	2 (3)
	Induration/Swelling	Any n (%)	2 (17)	1 (8)	1 (9)	2 (18)	2 (17)	3 (27)	N/A	11 (16)
		Mild n (%)	0 (0)	1 (8)	1 (9)	2 (18)	2 (17)	2 (18)	N/A	8 (12)
		Moderate n (%)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	N/A	3 (4)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

Program: Tsaf_locR_3-4.sas (Page 4 of 8)

Table 14.3.1-1.4-1: Frequency of subjects with solicited local reactions by grade - completers only - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=119)
Prime up to Day 7 after prime		nn	12	12	12	36	119
	Any	Any n (%)	7 (58)	11 (92)	11 (92)	29 (81)	96 (81)
		Mild n (%)	7 (58)	10 (83)	10 (83)	27 (75)	92 (77)
		Moderate n (%)	0 (0)	4 (33)	3 (25)	7 (19)	37 (31)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	10 (8)
	Pain	Any n (%)	6 (50)	7 (58)	9 (75)	22 (61)	78 (66)
		Mild n (%)	6 (50)	7 (58)	9 (75)	22 (61)	76 (64)
		Moderate n (%)	0 (0)	1 (8)	1 (8)	2 (6)	14 (12)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	9 (8)
	Tenderness	Any n (%)	7 (58)	10 (83)	10 (83)	27 (75)	92 (77)
		Mild n (%)	7 (58)	8 (67)	9 (75)	24 (67)	82 (69)
		Moderate n (%)	0 (0)	4 (33)	3 (25)	7 (19)	36 (30)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
	Erythema/Redness	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-1.4-1: Frequency of subjects with solicited local reactions by grade - completers only - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=119)
Prime up to Day 7 after prime	Erythema/Redness	Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Induration/Swelling	Any n (%)	0 (0)	2 (17)	1 (8)	3 (8)	10 (8)
		Mild n (%)	0 (0)	2 (17)	1 (8)	3 (8)	9 (8)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Boost up to Day 7 after boost		nn	12	11	12	35	104
	Any	Any n (%)	8 (67)	9 (82)	9 (75)	26 (74)	81 (78)
		Mild n (%)	8 (67)	9 (82)	8 (67)	25 (71)	76 (73)
		Moderate n (%)	3 (25)	3 (27)	6 (50)	12 (34)	38 (37)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
	Pain	Any n (%)	6 (50)	8 (73)	8 (67)	22 (63)	68 (65)
		Mild n (%)	6 (50)	8 (73)	7 (58)	21 (60)	61 (59)
		Moderate n (%)	2 (17)	1 (9)	4 (33)	7 (20)	30 (29)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-1.4-1: Frequency of subjects with solicited local reactions by grade - completers only - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=119)
Boost up to Day 7 after boost	Tenderness	Any n (%)	8 (67)	8 (73)	9 (75)	25 (71)	77 (74)
		Mild n (%)	8 (67)	8 (73)	8 (67)	24 (69)	70 (67)
		Moderate n (%)	2 (17)	3 (27)	6 (50)	11 (31)	35 (34)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
	Erythema/Redness	Any n (%)	2 (17)	0 (0)	2 (17)	4 (11)	7 (7)
		Mild n (%)	2 (17)	0 (0)	2 (17)	4 (11)	7 (7)
	Induration/Swelling	Any n (%)	2 (17)	3 (27)	2 (17)	7 (20)	13 (13)
		Mild n (%)	2 (17)	3 (27)	2 (17)	7 (20)	11 (11)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Combined interval		nn	12	11	12	35	104
	Any	Any n (%)	8 (67)	10 (91)	11 (92)	29 (83)	86 (83)
		Mild n (%)	8 (67)	10 (91)	11 (92)	29 (83)	86 (83)
		Moderate n (%)	3 (25)	5 (45)	7 (58)	15 (43)	51 (49)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	13 (13)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-1.4-1: Frequency of subjects with solicited local reactions by grade - completers only - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=119)
Combined interval	Pain	Any n (%)	7 (58)	9 (82)	10 (83)	26 (74)	78 (75)
		Mild n (%)	7 (58)	9 (82)	10 (83)	26 (74)	76 (73)
		Moderate n (%)	2 (17)	2 (18)	5 (42)	9 (26)	35 (34)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	10 (10)
	Tenderness	Any n (%)	8 (67)	9 (82)	10 (83)	27 (77)	83 (80)
		Mild n (%)	8 (67)	9 (82)	10 (83)	27 (77)	80 (77)
		Moderate n (%)	2 (17)	5 (45)	7 (58)	14 (40)	50 (48)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	10 (10)
	Erythema/Redness	Any n (%)	2 (17)	0 (0)	2 (17)	4 (11)	11 (11)
		Mild n (%)	2 (17)	0 (0)	2 (17)	4 (11)	11 (11)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Induration/Swelling	Any n (%)	2 (17)	3 (27)	3 (25)	8 (23)	19 (18)
		Mild n (%)	2 (17)	3 (27)	3 (25)	8 (23)	16 (15)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-1.5.1-1: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Local reactions	After prime	Time from dose to first local reaction [Days]	n	6	5	10	12	11	12	12	68
			Mean (SD)	1.0 (0.0)	1.0 (0.0)	1.4 (0.5)	1.2 (0.4)	1.0 (0.0)	1.3 (0.5)	1.0 (0.0)	1.1 (0.4)
			Min	1	1	1	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
			Max	1	1	2	2	1	2	1	2
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	1	2	4	2	1	10
			Mean (SD)	- (-)	- (-)	2.0 (-)	1.5 (-)	1.3 (0.5)	2.0 (-)	1.0 (-)	1.5 (0.5)
			Min	-	-	2	1	1	2	1	1
			Median	-	-	2.0	1.5	1.0	2.0	1.0	1.5
			Max	-	-	2	2	2	2	1	2
		Time from first local reaction to last local reaction [Days]	n	6	5	10	12	11	12	12	68
			Mean (SD)	1.5 (0.5)	3.2 (1.8)	2.9 (2.3)	2.7 (1.6)	3.7 (1.9)	3.1 (2.1)	3.1 (1.4)	3.0 (1.8)
			Min	1	2	1	1	1	1	2	1
			Median	1.5	2.0	2.0	2.5	3.0	2.0	2.5	2.0
			Max	2	6	8	5	7	7	6	8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.1-1: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Local reactions	After prime	Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	1	2	4	2	1	10
			Mean (SD)	- (-)	- (-)	1.0 (-)	1.0 (-)	1.3 (0.5)	1.0 (-)	2.0 (-)	1.2 (0.4)
			Min	-	-	1	1	1	1	2	1
			Median	-	-	1.0	1.0	1.0	1.0	2.0	1.0
			Max	-	-	1	1	2	1	2	2
	After boost	Time from dose to first local reaction [Days]	n	7	5	10	11	11	11	N/A	55
			Mean (SD)	2.0 (1.5)	1.0 (0.0)	1.0 (0.0)	1.0 (0.0)	1.0 (0.0)	1.1 (0.3)	N/A	1.1 (0.6)
			Min	1	1	1	1	1	1	N/A	1
			Median	1.0	1.0	1.0	1.0	1.0	1.0	N/A	1.0
			Max	5	1	1	1	1	2	N/A	5
		Time from dose to first local reaction with grade >= 3 [Days]	n	2	0	0	0	2	3	N/A	7
			Mean (SD)	1.5 (-)	- (-)	- (-)	- (-)	1.0 (-)	1.0 (0.0)	N/A	1.1 (0.4)
			Min	1	-	-	-	1	1	N/A	1
			Median	1.5	-	-	-	1.0	1.0	N/A	1.0
			Max	2	-	-	-	1	1	N/A	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.1-1: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Local reactions	After boost	Time from first local reaction to last local reaction [Days]	n	7	5	10	11	11	11	N/A	55
			Mean (SD)	2.0 (1.7)	4.6 (2.2)	3.1 (2.1)	3.6 (1.7)	3.5 (1.6)	3.5 (1.9)	N/A	3.3 (1.9)
			Min	1	1	1	1	1	1	N/A	1
			Median	1.0	6.0	2.5	4.0	3.0	3.0	N/A	3.0
			Max	5	6	8	7	7	7	N/A	8
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	2	0	0	0	2	3	N/A	7
			Mean (SD)	3.0 (-)	- (-)	- (-)	- (-)	1.0 (-)	1.7 (1.2)	N/A	1.9 (1.2)
			Min	2	-	-	-	1	1	N/A	1
			Median	3.0	-	-	-	1.0	1.0	N/A	1.0
			Max	4	-	-	-	1	3	N/A	4
Local or systemic reactions	After prime	Time from dose to first reaction [Days]	n	10	8	10	12	11	12	12	75
			Mean (SD)	1.0 (0.0)	1.4 (1.1)	1.3 (0.5)	1.1 (0.3)	1.0 (0.0)	1.2 (0.4)	1.0 (0.0)	1.1 (0.4)
			Min	1	1	1	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
			Max	1	4	2	2	1	2	1	4

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.1-1: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Local or systemic reactions	After prime	Time from dose to first reaction with grade >= 3 [Days]	n	0	0	1	3	5	5	8	22
			Mean (SD)	- (-)	- (-)	2.0 (-)	1.7 (0.6)	1.2 (0.4)	2.0 (0.0)	1.1 (0.4)	1.5 (0.5)
			Min	-	-	2	1	1	2	1	1
			Median	-	-	2.0	2.0	1.0	2.0	1.0	1.0
			Max	-	-	2	2	2	2	2	2
		Time from first reaction to last reaction [Days]	n	10	8	10	12	11	12	12	75
			Mean (SD)	2.6 (2.6)	3.8 (2.8)	3.4 (2.5)	3.8 (2.2)	4.4 (2.0)	3.9 (1.8)	3.5 (1.7)	3.6 (2.2)
			Min	1	1	1	1	1	1	2	1
			Median	1.0	2.5	2.5	4.0	4.0	4.0	3.0	3.0
			Max	7	8	9	7	7	7	7	9
		Time from first reaction with grade >= 3 to last reaction with grade >= 3 [Days]	n	0	0	1	3	5	5	8	22
			Mean (SD)	- (-)	- (-)	2.0 (-)	1.3 (0.6)	1.2 (0.4)	1.2 (0.4)	1.1 (0.4)	1.2 (0.4)
			Min	-	-	2	1	1	1	1	1
			Median	-	-	2.0	1.0	1.0	1.0	1.0	1.0
			Max	-	-	2	2	2	2	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.1-1: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Local or systemic reactions	After boost	Time from dose to first reaction [Days]	n	8	8	11	11	11	11	N/A	60
			Mean (SD)	1.3 (0.5)	1.3 (0.7)	1.1 (0.3)	1.0 (0.0)	1.0 (0.0)	1.1 (0.3)	N/A	1.1 (0.4)
			Min	1	1	1	1	1	1	N/A	1
			Median	1.0	1.0	1.0	1.0	1.0	1.0	N/A	1.0
			Max	2	3	2	1	1	2	N/A	3
		Time from dose to first reaction with grade >= 3 [Days]	n	3	1	5	5	6	6	N/A	26
			Mean (SD)	1.3 (0.6)	1.0 (-)	1.4 (0.5)	1.4 (0.5)	1.0 (0.0)	1.0 (0.0)	N/A	1.2 (0.4)
			Min	1	1	1	1	1	1	N/A	1
			Median	1.0	1.0	1.0	1.0	1.0	1.0	N/A	1.0
			Max	2	1	2	2	1	1	N/A	2
		Time from first reaction to last reaction [Days]	n	8	8	11	11	11	11	N/A	60
			Mean (SD)	3.4 (2.1)	3.9 (2.5)	4.3 (2.6)	4.4 (1.7)	3.9 (1.8)	3.7 (2.0)	N/A	4.0 (2.1)
			Min	1	1	1	2	2	1	N/A	1
			Median	3.0	5.0	3.0	4.0	4.0	4.0	N/A	4.0
			Max	6	6	8	7	7	7	N/A	8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.1-1: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Local or systemic reactions	After boost	Time from first reaction with grade >= 3 to last reaction with grade >= 3 [Days]	n	3	1	5	5	6	6	N/A	26
			Mean (SD)	3.0 (1.7)	1.0 (-)	1.0 (0.0)	1.4 (0.9)	1.3 (0.5)	2.0 (0.9)	N/A	1.6 (1.0)
			Min	1	1	1	1	1	1	N/A	1
			Median	4.0	1.0	1.0	1.0	1.0	2.0	N/A	1.0
			Max	4	1	1	3	2	3	N/A	4

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.1-1: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Local reactions	After prime	Time from dose to first local reaction [Days]	n	7	11	11	29	97
			Mean (SD)	1.0 (0.0)	1.2 (0.4)	1.1 (0.3)	1.1 (0.3)	1.1 (0.3)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	1	2	2	2	2
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	10
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.5 (0.5)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.5
			Max	-	-	-	-	2
		Time from first local reaction to last local reaction [Days]	n	7	11	11	29	97
			Mean (SD)	2.1 (0.4)	2.5 (1.1)	2.5 (1.0)	2.4 (0.9)	2.8 (1.6)
			Min	2	1	1	1	1
			Median	2.0	2.0	2.0	2.0	2.0
			Max	3	5	5	5	8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.1-1: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Local reactions	After prime	Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	10
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.2 (0.4)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	2
	After boost	Time from dose to first local reaction [Days]	n	8	9	9	26	81
			Mean (SD)	1.1 (0.4)	1.0 (0.0)	1.0 (0.0)	1.0 (0.2)	1.1 (0.5)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	2	1	1	2	5
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	7
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.1 (0.4)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.1-1: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Local reactions	After boost	Time from first local reaction to last local reaction [Days]	n	8	9	9	26	81
			Mean (SD)	4.6 (2.6)	3.4 (2.3)	3.3 (1.7)	3.8 (2.2)	3.5 (2.0)
			Min	1	1	2	1	1
			Median	5.5	3.0	3.0	3.0	3.0
			Max	7	8	7	8	8
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	7
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.9 (1.2)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	4
Local or systemic reactions	After prime	Time from dose to first reaction [Days]	n	9	12	12	33	108
			Mean (SD)	1.0 (0.0)	1.2 (0.4)	1.1 (0.3)	1.1 (0.3)	1.1 (0.4)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	1	2	2	2	4

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.1-1: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Local or systemic reactions	After prime	Time from dose to first reaction with grade >= 3 [Days]	n	1	1	2	4	26
			Mean (SD)	2.0 (-)	1.0 (-)	1.5 (-)	1.5 (0.6)	1.5 (0.5)
			Min	2	1	1	1	1
			Median	2.0	1.0	1.5	1.5	1.0
			Max	2	1	2	2	2
		Time from first reaction to last reaction [Days]	n	9	12	12	33	108
			Mean (SD)	3.0 (1.7)	3.3 (1.4)	3.3 (2.1)	3.2 (1.7)	3.5 (2.1)
			Min	1	2	1	1	1
			Median	3.0	3.0	3.0	3.0	3.0
			Max	7	6	7	7	9
		Time from first reaction with grade >= 3 to last reaction with grade >= 3 [Days]	n	1	1	2	4	26
			Mean (SD)	1.0 (-)	1.0 (-)	1.0 (-)	1.0 (0.0)	1.2 (0.4)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	1	1	1	1	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.1-1: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Local or systemic reactions	After boost	Time from dose to first reaction [Days]	n	9	10	12	31	91
			Mean (SD)	1.0 (0.0)	1.0 (0.0)	1.0 (0.0)	1.0 (0.0)	1.1 (0.3)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	1	1	1	1	3
		Time from dose to first reaction with grade >= 3 [Days]	n	2	2	4	8	34
			Mean (SD)	1.0 (-)	1.5 (-)	1.3 (0.5)	1.3 (0.5)	1.2 (0.4)
			Min	1	1	1	1	1
			Median	1.0	1.5	1.0	1.0	1.0
			Max	1	2	2	2	2
		Time from first reaction to last reaction [Days]	n	9	10	12	31	91
			Mean (SD)	4.3 (2.7)	3.6 (2.1)	3.5 (1.7)	3.8 (2.1)	3.9 (2.1)
			Min	1	1	2	1	1
			Median	6.0	3.0	3.0	3.0	3.0
			Max	7	8	7	8	8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.1-1: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Local or systemic reactions	After boost	Time from first reaction with grade >= 3 to last reaction with grade >= 3 [Days]	n	2	2	4	8	34
			Mean (SD)	1.5 (-)	1.0 (-)	1.5 (0.6)	1.4 (0.5)	1.6 (0.9)
			Min	1	1	1	1	1
			Median	1.5	1.0	1.5	1.0	1.0
			Max	2	1	2	2	4

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-1: Descriptive statistics of time of solicited local reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Pain	Time from dose to first local reaction [Days]	n	4	3	6	11	10	11	12	57
			Mean (SD)	1.0 (0.0)	1.0 (0.0)	1.7 (0.5)	1.2 (0.4)	1.2 (0.6)	1.4 (0.5)	1.0 (0.0)	1.2 (0.5)
			Min	1	1	1	1	1	1	1	1
			Median	1.0	1.0	2.0	1.0	1.0	1.0	1.0	1.0
			Max	1	1	2	2	3	2	1	3
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	1	2	3	2	1	9
			Mean (SD)	- (-)	- (-)	2.0 (-)	1.5 (-)	1.0 (0.0)	2.0 (-)	1.0 (-)	1.4 (0.5)
			Min	-	-	2	1	1	2	1	1
			Median	-	-	2.0	1.5	1.0	2.0	1.0	1.0
			Max	-	-	2	2	1	2	1	2
		Time from first local reaction to last local reaction [Days]	n	4	3	6	11	10	11	12	57
			Mean (SD)	1.5 (0.6)	2.0 (1.0)	3.0 (3.2)	2.1 (1.0)	2.9 (1.9)	2.9 (2.1)	2.8 (1.3)	2.6 (1.7)
			Min	1	1	1	1	1	1	1	1
			Median	1.5	2.0	1.0	2.0	2.0	2.0	2.5	2.0
			Max	2	3	8	4	6	7	6	8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-1: Descriptive statistics of time of solicited local reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Pain	Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	1	2	3	2	1	9
			Mean (SD)	- (-)	- (-)	1.0 (-)	1.0 (-)	1.3 (0.6)	1.0 (-)	2.0 (-)	1.2 (0.4)
			Min	-	-	1	1	1	1	2	1
			Median	-	-	1.0	1.0	1.0	1.0	2.0	1.0
			Max	-	-	1	1	2	1	2	2
	Tenderness	Time from dose to first local reaction [Days]	n	6	5	10	11	11	12	11	66
			Mean (SD)	1.0 (0.0)	1.0 (0.0)	1.5 (0.5)	1.2 (0.4)	1.0 (0.0)	1.4 (0.5)	1.1 (0.3)	1.2 (0.4)
			Min	1	1	1	1	1	1	1	1
			Median	1.0	1.0	1.5	1.0	1.0	1.0	1.0	1.0
			Max	1	1	2	2	1	2	2	2
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	1	1	3	1	0	6
			Mean (SD)	- (-)	- (-)	2.0 (-)	1.0 (-)	1.3 (0.6)	2.0 (-)	- (-)	1.5 (0.5)
			Min	-	-	2	1	1	2	-	1
			Median	-	-	2.0	1.0	1.0	2.0	-	1.5
			Max	-	-	2	1	2	2	-	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-1: Descriptive statistics of time of solicited local reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Tenderness	Time from first local reaction to last local reaction [Days]	n	6	5	10	11	11	12	11	66
			Mean (SD)	1.5 (0.5)	3.2 (1.8)	2.4 (2.1)	2.8 (1.5)	3.6 (1.7)	2.9 (2.1)	3.1 (1.5)	2.9 (1.8)
			Min	1	2	1	1	1	1	1	1
			Median	1.5	2.0	2.0	3.0	3.0	2.0	3.0	2.0
			Max	2	6	8	5	6	7	6	8
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	1	1	3	1	0	6
			Mean (SD)	- (-)	- (-)	1.0 (-)	1.0 (-)	1.0 (0.0)	1.0 (-)	- (-)	1.0 (0.0)
			Min	-	-	1	1	1	1	-	1
			Median	-	-	1.0	1.0	1.0	1.0	-	1.0
			Max	-	-	1	1	1	1	-	1
	Erythema/Redness	Time from dose to first local reaction [Days]	n	0	0	0	0	3	3	0	6
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	2.3 (0.6)	2.0 (1.0)	- (-)	2.2 (0.8)
			Min	-	-	-	-	2	1	-	1
			Median	-	-	-	-	2.0	2.0	-	2.0
			Max	-	-	-	-	3	3	-	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-1: Descriptive statistics of time of solicited local reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Erythema/Redness	Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-	-	-
			Median	-	-	-	-	-	-	-	-
			Max	-	-	-	-	-	-	-	-
		Time from first local reaction to last local reaction [Days]	n	0	0	0	0	3	3	0	6
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	4.3 (2.1)	4.3 (1.2)	- (-)	4.3 (1.5)
			Min	-	-	-	-	2	3	-	2
			Median	-	-	-	-	5.0	5.0	-	5.0
			Max	-	-	-	-	6	5	-	6
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-	-	-
			Median	-	-	-	-	-	-	-	-
			Max	-	-	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-1: Descriptive statistics of time of solicited local reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Induration/Swelling	Time from dose to first local reaction [Days]	n	0	0	0	1	2	3	1	7
			Mean (SD)	- (-)	- (-)	- (-)	2.0 (-)	1.5 (-)	1.7 (0.6)	1.0 (-)	1.6 (0.5)
			Min	-	-	-	2	1	1	1	1
			Median	-	-	-	2.0	1.5	2.0	1.0	2.0
			Max	-	-	-	2	2	2	1	2
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-	-	-
			Median	-	-	-	-	-	-	-	-
			Max	-	-	-	-	-	-	-	-
		Time from first local reaction to last local reaction [Days]	n	0	0	0	1	2	3	1	7
			Mean (SD)	- (-)	- (-)	- (-)	1.0 (-)	6.0 (-)	3.7 (0.6)	4.0 (-)	4.0 (1.8)
			Min	-	-	-	1	5	3	4	1
			Median	-	-	-	1.0	6.0	4.0	4.0	4.0
			Max	-	-	-	1	7	4	4	7

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-1: Descriptive statistics of time of solicited local reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Induration/Swelling	Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-	-	-
			Median	-	-	-	-	-	-	-	-
			Max	-	-	-	-	-	-	-	-
After boost	Pain	Time from dose to first local reaction [Days]	n	6	3	7	8	11	11	N/A	46
			Mean (SD)	1.8 (1.6)	2.7 (2.9)	1.0 (0.0)	1.0 (0.0)	1.0 (0.0)	1.1 (0.3)	N/A	1.2 (0.9)
			Min	1	1	1	1	1	1	N/A	1
			Median	1.0	1.0	1.0	1.0	1.0	1.0	N/A	1.0
			Max	5	6	1	1	1	2	N/A	6
		Time from dose to first local reaction with grade >= 3 [Days]	n	1	0	0	0	2	2	N/A	5
			Mean (SD)	3.0 (-)	- (-)	- (-)	- (-)	1.0 (-)	1.0 (-)	N/A	1.4 (0.9)
			Min	3	-	-	-	1	1	N/A	1
			Median	3.0	-	-	-	1.0	1.0	N/A	1.0
			Max	3	-	-	-	1	1	N/A	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-1: Descriptive statistics of time of solicited local reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Pain	Time from first local reaction to last local reaction [Days]	n	6	3	7	8	11	11	N/A	46
			Mean (SD)	2.2 (1.8)	3.3 (2.5)	2.6 (1.4)	3.3 (1.8)	2.6 (1.0)	3.2 (2.1)	N/A	2.8 (1.7)
			Min	1	1	1	1	1	1	N/A	1
			Median	1.0	3.0	2.0	3.0	2.0	2.0	N/A	2.0
			Max	5	6	5	6	4	7	N/A	7
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	1	0	0	0	2	2	N/A	5
			Mean (SD)	3.0 (-)	- (-)	- (-)	- (-)	1.0 (-)	2.0 (-)	N/A	1.8 (1.1)
			Min	3	-	-	-	1	1	N/A	1
			Median	3.0	-	-	-	1.0	2.0	N/A	1.0
			Max	3	-	-	-	1	3	N/A	3
	Tenderness	Time from dose to first local reaction [Days]	n	6	5	9	11	10	11	N/A	52
			Mean (SD)	2.2 (1.6)	1.0 (0.0)	1.0 (0.0)	1.0 (0.0)	1.0 (0.0)	1.1 (0.3)	N/A	1.2 (0.6)
			Min	1	1	1	1	1	1	N/A	1
			Median	1.5	1.0	1.0	1.0	1.0	1.0	N/A	1.0
			Max	5	1	1	1	1	2	N/A	5

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-1: Descriptive statistics of time of solicited local reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Tenderness	Time from dose to first local reaction with grade >= 3 [Days]	n	2	0	0	0	1	2	N/A	5
			Mean (SD)	1.5 (-)	- (-)	- (-)	- (-)	1.0 (-)	1.0 (-)	N/A	1.2 (0.4)
			Min	1	-	-	-	1	1	N/A	1
			Median	1.5	-	-	-	1.0	1.0	N/A	1.0
			Max	2	-	-	-	1	1	N/A	2
		Time from first local reaction to last local reaction [Days]	n	6	5	9	11	10	11	N/A	52
			Mean (SD)	2.0 (1.7)	4.6 (2.2)	3.3 (2.1)	3.5 (1.8)	3.5 (1.6)	3.4 (1.9)	N/A	3.4 (1.9)
			Min	1	1	1	1	2	1	N/A	1
			Median	1.0	6.0	3.0	3.0	3.0	3.0	N/A	3.0
			Max	5	6	8	7	7	7	N/A	8
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	2	0	0	0	1	2	N/A	5
			Mean (SD)	3.0 (-)	- (-)	- (-)	- (-)	1.0 (-)	2.0 (-)	N/A	2.2 (1.3)
			Min	2	-	-	-	1	1	N/A	1
			Median	3.0	-	-	-	1.0	2.0	N/A	2.0
			Max	4	-	-	-	1	3	N/A	4

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-1: Descriptive statistics of time of solicited local reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Erythema/Redness	Time from dose to first local reaction [Days]	n	0	1	0	1	0	1	N/A	3
			Mean (SD)	- (-)	6.0 (-)	- (-)	3.0 (-)	- (-)	3.0 (-)	N/A	4.0 (1.7)
			Min	-	6	-	3	-	3	N/A	3
			Median	-	6.0	-	3.0	-	3.0	N/A	3.0
			Max	-	6	-	3	-	3	N/A	6
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0	N/A	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	N/A	- (-)
			Min	-	-	-	-	-	-	N/A	-
			Median	-	-	-	-	-	-	N/A	-
			Max	-	-	-	-	-	-	N/A	-
		Time from first local reaction to last local reaction [Days]	n	0	1	0	1	0	1	N/A	3
			Mean (SD)	- (-)	1.0 (-)	- (-)	2.0 (-)	- (-)	3.0 (-)	N/A	2.0 (1.0)
			Min	-	1	-	2	-	3	N/A	1
			Median	-	1.0	-	2.0	-	3.0	N/A	2.0
			Max	-	1	-	2	-	3	N/A	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-1: Descriptive statistics of time of solicited local reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Erythema/Redness	Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0	N/A	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	N/A	- (-)
			Min	-	-	-	-	-	-	N/A	-
			Median	-	-	-	-	-	-	N/A	-
			Max	-	-	-	-	-	-	N/A	-
	Induration/Swelling	Time from dose to first local reaction [Days]	n	2	1	1	1	0	1	N/A	6
			Mean (SD)	2.0 (-)	6.0 (-)	2.0 (-)	1.0 (-)	- (-)	1.0 (-)	N/A	2.3 (1.9)
			Min	2	6	2	1	-	1	N/A	1
			Median	2.0	6.0	2.0	1.0	-	1.0	N/A	2.0
			Max	2	6	2	1	-	1	N/A	6
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0	N/A	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	N/A	- (-)
			Min	-	-	-	-	-	-	N/A	-
			Median	-	-	-	-	-	-	N/A	-
			Max	-	-	-	-	-	-	N/A	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-1: Descriptive statistics of time of solicited local reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Induration/Swelling	Time from first local reaction to last local reaction [Days]	n	2	1	1	1	0	1	N/A	6
			Mean (SD)	1.0 (-)	1.0 (-)	1.0 (-)	2.0 (-)	- (-)	2.0 (-)	N/A	1.3 (0.5)
			Min	1	1	1	2	-	2	N/A	1
			Median	1.0	1.0	1.0	2.0	-	2.0	N/A	1.0
			Max	1	1	1	2	-	2	N/A	2
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0	N/A	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	N/A	- (-)
			Min	-	-	-	-	-	-	N/A	-
			Median	-	-	-	-	-	-	N/A	-
			Max	-	-	-	-	-	-	N/A	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-1: Descriptive statistics of time of solicited local reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Pain	Time from dose to first local reaction [Days]	n	6	7	9	22	79
			Mean (SD)	1.3 (0.5)	1.3 (0.5)	1.1 (0.3)	1.2 (0.4)	1.2 (0.4)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	2	2	2	2	3
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	9
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.4 (0.5)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	2
		Time from first local reaction to last local reaction [Days]	n	6	7	9	22	79
			Mean (SD)	1.7 (0.8)	2.7 (1.1)	2.2 (1.0)	2.2 (1.0)	2.5 (1.6)
			Min	1	2	1	1	1
			Median	1.5	2.0	2.0	2.0	2.0
			Max	3	5	4	5	8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-1: Descriptive statistics of time of solicited local reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Pain	Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	9
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.2 (0.4)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	2
	Tenderness	Time from dose to first local reaction [Days]	n	7	10	10	27	93
			Mean (SD)	1.0 (0.0)	1.2 (0.4)	1.1 (0.3)	1.1 (0.3)	1.2 (0.4)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	1	2	2	2	2
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	6
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.5 (0.5)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.5
			Max	-	-	-	-	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-1: Descriptive statistics of time of solicited local reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Tenderness	Time from first local reaction to last local reaction [Days]	n	7	10	10	27	93
			Mean (SD)	2.1 (0.4)	2.4 (1.0)	2.6 (1.0)	2.4 (0.8)	2.7 (1.6)
			Min	2	1	2	1	1
			Median	2.0	2.0	2.0	2.0	2.0
			Max	3	4	5	5	8
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	6
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (0.0)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	1
	Erythema/Redness	Time from dose to first local reaction [Days]	n	0	0	0	0	6
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	2.2 (0.8)
			Min	-	-	-	-	1
			Median	-	-	-	-	2.0
			Max	-	-	-	-	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-1: Descriptive statistics of time of solicited local reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Erythema/Redness	Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from first local reaction to last local reaction [Days]	n	0	0	0	0	6
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	4.3 (1.5)
			Min	-	-	-	-	2
			Median	-	-	-	-	5.0
			Max	-	-	-	-	6
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-1: Descriptive statistics of time of solicited local reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Induration/Swelling	Time from dose to first local reaction [Days]	n	0	2	1	3	10
			Mean (SD)	- (-)	1.0 (-)	1.0 (-)	1.0 (0.0)	1.4 (0.5)
			Min	-	1	1	1	1
			Median	-	1.0	1.0	1.0	1.0
			Max	-	1	1	1	2
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from first local reaction to last local reaction [Days]	n	0	2	1	3	10
			Mean (SD)	- (-)	1.5 (-)	3.0 (-)	2.0 (1.0)	3.4 (1.8)
			Min	-	1	3	1	1
			Median	-	1.5	3.0	2.0	3.5
			Max	-	2	3	3	7

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-1: Descriptive statistics of time of solicited local reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Induration/Swelling	Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
After boost	Pain	Time from dose to first local reaction [Days]	n	6	8	8	22	68
			Mean (SD)	1.2 (0.4)	1.1 (0.4)	1.0 (0.0)	1.1 (0.3)	1.2 (0.8)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	2	2	1	2	6
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	5
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.4 (0.9)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-1: Descriptive statistics of time of solicited local reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After boost	Pain	Time from first local reaction to last local reaction [Days]	n	6	8	8	22	68
			Mean (SD)	3.8 (2.4)	3.1 (2.3)	3.1 (1.7)	3.3 (2.1)	3.0 (1.8)
			Min	1	1	2	1	1
			Median	4.0	2.5	2.5	2.5	2.0
			Max	6	8	7	8	8
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	5
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.8 (1.1)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	3
	Tenderness	Time from dose to first local reaction [Days]	n	8	8	9	25	77
			Mean (SD)	1.3 (0.5)	1.4 (1.1)	1.0 (0.0)	1.2 (0.6)	1.2 (0.6)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	2	4	1	4	5

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-1: Descriptive statistics of time of solicited local reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After boost	Tenderness	Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	5
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.2 (0.4)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	2
		Time from first local reaction to last local reaction [Days]	n	8	8	9	25	77
			Mean (SD)	3.3 (2.6)	3.3 (1.8)	3.2 (1.6)	3.2 (1.9)	3.3 (1.9)
			Min	1	1	2	1	1
			Median	2.0	3.0	3.0	3.0	3.0
			Max	7	6	7	7	8
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	5
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	2.2 (1.3)
			Min	-	-	-	-	1
			Median	-	-	-	-	2.0
			Max	-	-	-	-	4

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-1: Descriptive statistics of time of solicited local reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After boost	Erythema/Redness	Time from dose to first local reaction [Days]	n	2	0	2	4	7
			Mean (SD)	3.5 (-)	- (-)	3.0 (-)	3.3 (1.3)	3.6 (1.4)
			Min	2	-	3	2	2
			Median	3.5	-	3.0	3.0	3.0
			Max	5	-	3	5	6
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from first local reaction to last local reaction [Days]	n	2	0	2	4	7
			Mean (SD)	4.0 (-)	- (-)	2.0 (-)	3.0 (1.6)	2.6 (1.4)
			Min	3	-	1	1	1
			Median	4.0	-	2.0	3.0	3.0
			Max	5	-	3	5	5

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-1: Descriptive statistics of time of solicited local reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After boost	Erythema/Redness	Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
	Induration/Swelling	Time from dose to first local reaction [Days]	n	2	3	2	7	13
			Mean (SD)	1.5 (-)	1.7 (0.6)	3.5 (-)	2.1 (1.1)	2.2 (1.4)
			Min	1	1	3	1	1
			Median	1.5	2.0	3.5	2.0	2.0
			Max	2	2	4	4	6
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-1: Descriptive statistics of time of solicited local reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After boost	Induration/Swelling	Time from first local reaction to last local reaction [Days]	n	2	3	2	7	13
			Mean (SD)	4.0 (-)	1.3 (0.6)	2.5 (-)	2.4 (2.3)	1.9 (1.8)
			Min	1	1	1	1	1
			Median	4.0	1.0	2.5	1.0	1.0
			Max	7	2	4	7	7
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.6.1-1: Frequency of subjects with solicited local and any solicited reactions per day - BNT162b1

Safety set

			Younger dose ranging cohorts							
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Local reactions	After prime	Any n	6	5	10	12	11	12	12	68
		Day 0 n (%)	6 (100)	5 (100)	6 (60)	10 (83)	11 (100)	8 (67)	12 (100)	58 (85)
		Day 1 n (%)	3 (50)	5 (100)	10 (100)	10 (83)	10 (91)	11 (92)	12 (100)	61 (90)
		Day 2 n (%)	0 (0)	2 (40)	4 (40)	6 (50)	7 (64)	6 (50)	6 (50)	31 (46)
		Day 3 n (%)	0 (0)	2 (40)	2 (20)	4 (33)	4 (36)	5 (42)	4 (33)	21 (31)
		Day 4 n (%)	0 (0)	1 (20)	2 (20)	2 (17)	2 (18)	4 (33)	2 (17)	13 (19)
		Day 5 n (%)	0 (0)	1 (20)	2 (20)	0 (0)	3 (27)	2 (17)	1 (8)	9 (13)
		Day 6 n (%)	0 (0)	0 (0)	1 (10)	0 (0)	1 (9)	1 (8)	0 (0)	3 (4)
		Day 7 n (%)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	After boost	Any n	7	5	10	11	11	11	N/A	55
		Day 0 n (%)	4 (57)	5 (100)	10 (100)	11 (100)	11 (100)	10 (91)	N/A	51 (93)
		Day 1 n (%)	2 (29)	4 (80)	8 (80)	8 (73)	10 (91)	11 (100)	N/A	43 (78)
		Day 2 n (%)	3 (43)	3 (60)	5 (50)	9 (82)	7 (64)	6 (55)	N/A	33 (60)
		Day 3 n (%)	2 (29)	2 (40)	3 (30)	6 (55)	4 (36)	5 (45)	N/A	22 (40)
		Day 4 n (%)	2 (29)	1 (20)	2 (20)	3 (27)	2 (18)	3 (27)	N/A	13 (24)
		Day 5 n (%)	1 (14)	3 (60)	1 (10)	1 (9)	0 (0)	2 (18)	N/A	8 (15)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 1 of 6)

Table 14.3.1-1.6.1-1: Frequency of subjects with solicited local and any solicited reactions per day - BNT162b1

Safety set

			Younger dose ranging cohorts							
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Local reactions	After boost	Day 6 n (%)	0 (0)	0 (0)	1 (10)	1 (9)	1 (9)	1 (9)	N/A	4 (7)
		Day 7 n (%)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	N/A	1 (2)
Local or systemic reactions	After prime	Any n	10	8	10	12	11	12	12	75
		Day 0 n (%)	10 (100)	7 (88)	7 (70)	11 (92)	11 (100)	10 (83)	12 (100)	68 (91)
		Day 1 n (%)	3 (30)	5 (63)	10 (100)	10 (83)	10 (91)	12 (100)	12 (100)	62 (83)
		Day 2 n (%)	1 (10)	3 (38)	5 (50)	7 (58)	8 (73)	8 (67)	7 (58)	39 (52)
		Day 3 n (%)	1 (10)	3 (38)	2 (20)	6 (50)	5 (45)	7 (58)	5 (42)	29 (39)
		Day 4 n (%)	0 (0)	2 (25)	3 (30)	3 (25)	3 (27)	5 (42)	2 (17)	18 (24)
		Day 5 n (%)	3 (30)	2 (25)	2 (20)	3 (25)	4 (36)	3 (25)	1 (8)	18 (24)
		Day 6 n (%)	1 (10)	2 (25)	1 (10)	1 (8)	2 (18)	1 (8)	1 (8)	9 (12)
		Day 7 n (%)	0 (0)	1 (13)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	2 (3)
		Day missing n	0	0	1	0	0	0	0	1
	After boost	Any n	8	8	11	11	11	11	N/A	60
		Day 0 n (%)	6 (75)	7 (88)	10 (91)	11 (100)	11 (100)	10 (91)	N/A	55 (92)
		Day 1 n (%)	6 (75)	4 (50)	10 (91)	11 (100)	11 (100)	11 (100)	N/A	53 (88)
		Day 2 n (%)	4 (50)	4 (50)	8 (73)	10 (91)	7 (64)	7 (64)	N/A	40 (67)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 2 of 6)

Table 14.3.1-1.6.1-1: Frequency of subjects with solicited local and any solicited reactions per day - BNT162b1

Safety set

			Younger dose ranging cohorts							
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Local or systemic reactions	After boost	Day 3 n (%)	3 (38)	2 (25)	4 (36)	6 (55)	5 (45)	6 (55)	N/A	26 (43)
		Day 4 n (%)	4 (50)	3 (38)	3 (27)	3 (27)	3 (27)	3 (27)	N/A	19 (32)
		Day 5 n (%)	2 (25)	5 (63)	3 (27)	3 (27)	1 (9)	3 (27)	N/A	17 (28)
		Day 6 n (%)	0 (0)	0 (0)	3 (27)	2 (18)	2 (18)	1 (9)	N/A	8 (13)
		Day 7 n (%)	0 (0)	0 (0)	3 (27)	0 (0)	0 (0)	0 (0)	N/A	3 (5)
		Day missing n	0	0	1	0	0	0	N/A	1

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 3 of 6)

Table 14.3.1-1.6.1-1: Frequency of subjects with solicited local and any solicited reactions per day - BNT162b1

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=29)	Total (N=120)
Local reactions	After prime	Any n	7	11	11	29	97
		Day 0 n (%)	7 (100)	9 (82)	10 (91)	26 (90)	84 (87)
		Day 1 n (%)	7 (100)	11 (100)	10 (91)	28 (97)	89 (92)
		Day 2 n (%)	1 (14)	4 (36)	5 (45)	10 (34)	41 (42)
		Day 3 n (%)	0 (0)	3 (27)	1 (9)	4 (14)	25 (26)
		Day 4 n (%)	0 (0)	1 (9)	1 (9)	2 (7)	15 (15)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	9 (9)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	After boost	Any n	8	9	9	26	81
		Day 0 n (%)	6 (75)	9 (100)	9 (100)	24 (92)	75 (93)
		Day 1 n (%)	7 (88)	7 (78)	9 (100)	23 (88)	66 (81)
		Day 2 n (%)	5 (63)	6 (67)	6 (67)	17 (65)	50 (62)
		Day 3 n (%)	5 (63)	3 (33)	2 (22)	10 (38)	32 (40)
		Day 4 n (%)	5 (63)	2 (22)	2 (22)	9 (35)	22 (27)
		Day 5 n (%)	5 (63)	2 (22)	1 (11)	8 (31)	16 (20)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 1 of 6)

Table 14.3.1-1.6.1-1: Frequency of subjects with solicited local and any solicited reactions per day - BNT162b1

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=29)	Total (N=120)
Local reactions	After boost	Day 6 n (%)	3 (38)	1 (11)	1 (11)	5 (19)	9 (11)
		Day 7 n (%)	0 (0)	1 (11)	0 (0)	1 (4)	2 (2)
Local or systemic reactions	After prime	Any n	9	12	12	33	10
		Day 0 n (%)	9 (100)	10 (83)	11 (92)	30 (91)	98 (91)
		Day 1 n (%)	8 (89)	12 (100)	10 (83)	30 (91)	92 (85)
		Day 2 n (%)	4 (44)	8 (67)	7 (58)	19 (58)	58 (54)
		Day 3 n (%)	2 (22)	6 (50)	3 (25)	11 (33)	40 (37)
		Day 4 n (%)	1 (11)	3 (25)	2 (17)	6 (18)	24 (22)
		Day 5 n (%)	0 (0)	1 (8)	1 (8)	2 (6)	20 (19)
		Day 6 n (%)	1 (11)	0 (0)	2 (17)	3 (9)	12 (11)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Day missing n	0	0	0	0	1
	After boost	Any n	9	10	12	31	91
		Day 0 n (%)	8 (89)	10 (100)	11 (92)	29 (94)	84 (92)
		Day 1 n (%)	7 (78)	9 (90)	12 (100)	28 (90)	81 (89)
		Day 2 n (%)	5 (56)	7 (70)	10 (83)	22 (71)	62 (68)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 2 of 6)

Table 14.3.1-1.6.1-1: Frequency of subjects with solicited local and any solicited reactions per day - BNT162b1

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=29)	Total (N=120)
Local or systemic reactions	After boost	Day 3 n (%)	5 (56)	4 (40)	2 (17)	11 (35)	37 (41)
		Day 4 n (%)	5 (56)	2 (20)	2 (17)	9 (29)	28 (31)
		Day 5 n (%)	5 (56)	2 (20)	2 (17)	9 (29)	26 (29)
		Day 6 n (%)	3 (33)	1 (10)	2 (17)	6 (19)	14 (15)
		Day 7 n (%)	0 (0)	1 (10)	0 (0)	1 (3)	4 (4)
		Day missing n	0	0	0	0	1

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 3 of 6)

Table 14.3.1-1.6.2-1: Frequency of subjects with solicited local reactions by term per day - BNT162b1

Safety set

			Younger dose ranging cohorts							
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Pain	Any n	4	3	6	11	10	11	12	57
		Day 0 n (%)	4 (100)	3 (100)	2 (33)	9 (82)	9 (90)	7 (64)	12 (100)	46 (81)
		Day 1 n (%)	2 (50)	2 (67)	5 (83)	9 (82)	7 (70)	11 (100)	11 (92)	47 (82)
		Day 2 n (%)	0 (0)	1 (33)	2 (33)	4 (36)	5 (50)	5 (45)	6 (50)	23 (40)
		Day 3 n (%)	0 (0)	0 (0)	2 (33)	1 (9)	3 (30)	3 (27)	3 (25)	12 (21)
		Day 4 n (%)	0 (0)	0 (0)	2 (33)	0 (0)	2 (20)	3 (27)	1 (8)	8 (14)
		Day 5 n (%)	0 (0)	0 (0)	2 (33)	0 (0)	2 (20)	2 (18)	1 (8)	7 (12)
		Day 6 n (%)	0 (0)	0 (0)	1 (17)	0 (0)	0 (0)	1 (9)	0 (0)	2 (4)
		Day 7 n (%)	0 (0)	0 (0)	1 (17)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
	Tenderness	Any n	6	5	10	11	11	12	11	66
		Day 0 n (%)	6 (100)	5 (100)	5 (50)	9 (82)	11 (100)	7 (58)	10 (91)	53 (80)
		Day 1 n (%)	3 (50)	5 (100)	10 (100)	10 (91)	10 (91)	11 (92)	11 (100)	60 (91)
		Day 2 n (%)	0 (0)	2 (40)	3 (30)	6 (55)	7 (64)	6 (50)	6 (55)	30 (45)
		Day 3 n (%)	0 (0)	2 (40)	1 (10)	4 (36)	4 (36)	5 (42)	4 (36)	20 (30)
		Day 4 n (%)	0 (0)	1 (20)	1 (10)	2 (18)	2 (18)	3 (25)	2 (18)	11 (17)
		Day 5 n (%)	0 (0)	1 (20)	1 (10)	0 (0)	3 (27)	2 (17)	1 (9)	8 (12)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 1 of 10)

Table 14.3.1-1.6.2-1: Frequency of subjects with solicited local reactions by term per day - BNT162b1

Safety set

			Younger dose ranging cohorts							
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Tenderness	Day 6 n (%)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	1 (8)	0 (0)	2 (3)
		Day 7 n (%)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
	Erythema/Redness	Any n	0	0	0	0	3	3	0	6
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (33)	0 (0)	1 (17)
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (67)	1 (33)	0 (0)	3 (50)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (100)	3 (100)	0 (0)	6 (100)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (100)	3 (100)	0 (0)	6 (100)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (67)	3 (100)	0 (0)	5 (83)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (67)	1 (33)	0 (0)	3 (50)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (33)	0 (0)	0 (0)	1 (17)
	Induration/Swelling	Any n	0	0	0	1	2	3	1	7
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (50)	1 (33)	1 (100)	3 (43)
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	1 (100)	1 (50)	2 (67)	1 (100)	5 (71)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (50)	3 (100)	1 (100)	5 (71)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (100)	3 (100)	1 (100)	6 (86)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (100)	1 (33)	0 (0)	3 (43)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

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Table 14.3.1-1.6.2-1: Frequency of subjects with solicited local reactions by term per day - BNT162b1

Safety set

			Younger dose ranging cohorts							
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Induration/Swelling	Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (100)	0 (0)	0 (0)	2 (29)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	1 (14)
After boost	Pain	Any n	6	3	7	8	11	11	N/A	46
		Day 0 n (%)	4 (67)	2 (67)	7 (100)	8 (100)	11 (100)	10 (91)	N/A	42 (91)
		Day 1 n (%)	2 (33)	1 (33)	6 (86)	5 (63)	10 (91)	9 (82)	N/A	33 (72)
		Day 2 n (%)	2 (33)	1 (33)	2 (29)	6 (75)	5 (45)	5 (45)	N/A	21 (46)
		Day 3 n (%)	2 (33)	0 (0)	2 (29)	3 (38)	3 (27)	5 (45)	N/A	15 (33)
		Day 4 n (%)	2 (33)	0 (0)	1 (14)	2 (25)	0 (0)	3 (27)	N/A	8 (17)
		Day 5 n (%)	1 (17)	2 (67)	0 (0)	1 (13)	0 (0)	2 (18)	N/A	6 (13)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	N/A	1 (2)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
	Tenderness	Any n	6	5	9	11	10	11	N/A	52
		Day 0 n (%)	3 (50)	5 (100)	9 (100)	11 (100)	10 (100)	10 (91)	N/A	48 (92)
		Day 1 n (%)	2 (33)	4 (80)	8 (89)	8 (73)	10 (100)	11 (100)	N/A	43 (83)
		Day 2 n (%)	3 (50)	3 (60)	5 (56)	9 (82)	6 (60)	6 (55)	N/A	32 (62)
		Day 3 n (%)	1 (17)	2 (40)	3 (33)	5 (45)	3 (30)	5 (45)	N/A	19 (37)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 3 of 10)

Table 14.3.1-1.6.2-1: Frequency of subjects with solicited local reactions by term per day - BNT162b1

Safety set

			Younger dose ranging cohorts							
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Tenderness	Day 4 n (%)	2 (33)	1 (20)	2 (22)	3 (27)	2 (20)	2 (18)	N/A	12 (23)
		Day 5 n (%)	1 (17)	3 (60)	1 (11)	1 (9)	0 (0)	2 (18)	N/A	8 (15)
		Day 6 n (%)	0 (0)	0 (0)	1 (11)	1 (9)	1 (10)	1 (9)	N/A	4 (8)
		Day 7 n (%)	0 (0)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)	N/A	1 (2)
	Erythema/Redness	Any n	0	1	0	1	0	1	N/A	3
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	1 (100)	N/A	2 (67)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	1 (100)	N/A	2 (67)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	N/A	1 (33)
		Day 5 n (%)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (33)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
	Induration/Swelling	Any n	2	1	1	1	0	1	N/A	6
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	1 (100)	N/A	2 (33)
		Day 1 n (%)	2 (100)	0 (0)	1 (100)	1 (100)	0 (0)	1 (100)	N/A	5 (83)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

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Table 14.3.1-1.6.2-1: Frequency of subjects with solicited local reactions by term per day - BNT162b1

Safety set

			Younger dose ranging cohorts							
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Induration/Swelling	Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
		Day 5 n (%)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (17)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 5 of 10)

Table 14.3.1-1.6.2-1: Frequency of subjects with solicited local reactions by term per day - BNT162b1

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=29)	Total (N=120)
After prime	Pain	Any n	6	7	9	22	79
		Day 0 n (%)	4 (67)	5 (71)	8 (89)	17 (77)	63 (80)
		Day 1 n (%)	5 (83)	7 (100)	8 (89)	20 (91)	67 (85)
		Day 2 n (%)	1 (17)	4 (57)	3 (33)	8 (36)	31 (39)
		Day 3 n (%)	0 (0)	2 (29)	1 (11)	3 (14)	15 (19)
		Day 4 n (%)	0 (0)	1 (14)	0 (0)	1 (5)	9 (11)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	7 (9)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (3)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Tenderness	Any n	7	10	10	27	93
		Day 0 n (%)	7 (100)	8 (80)	9 (90)	24 (89)	77 (83)
		Day 1 n (%)	7 (100)	10 (100)	10 (100)	27 (100)	87 (94)
		Day 2 n (%)	1 (14)	3 (30)	5 (50)	9 (33)	39 (42)
		Day 3 n (%)	0 (0)	2 (20)	1 (10)	3 (11)	23 (25)
		Day 4 n (%)	0 (0)	1 (10)	1 (10)	2 (7)	13 (14)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	8 (9)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 6 of 10)

Table 14.3.1-1.6.2-1: Frequency of subjects with solicited local reactions by term per day - BNT162b1

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=29)	Total (N=120)
After prime	Tenderness	Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Erythema/Redness	Any n	0	0	0	0	6
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (17)
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (50)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	6 (100)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	6 (100)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	5 (83)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (50)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (17)
	Induration/Swelling	Any n	0	2	1	3	1
		Day 0 n (%)	0 (0)	2 (100)	1 (100)	3 (100)	6 (60)
		Day 1 n (%)	0 (0)	1 (50)	1 (100)	2 (67)	7 (70)
		Day 2 n (%)	0 (0)	0 (0)	1 (100)	1 (33)	6 (60)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	6 (60)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (30)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

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Table 14.3.1-1.6.2-1: Frequency of subjects with solicited local reactions by term per day - BNT162b1

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=29)	Total (N=120)
After prime	Induration/Swelling	Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (20)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)
After boost	Pain	Any n	6	8	8	22	68
		Day 0 n (%)	4 (67)	7 (88)	8 (100)	19 (86)	61 (90)
		Day 1 n (%)	6 (100)	6 (75)	8 (100)	20 (91)	53 (78)
		Day 2 n (%)	3 (50)	5 (63)	4 (50)	12 (55)	33 (49)
		Day 3 n (%)	3 (50)	3 (38)	2 (25)	8 (36)	23 (34)
		Day 4 n (%)	3 (50)	1 (13)	1 (13)	5 (23)	13 (19)
		Day 5 n (%)	3 (50)	1 (13)	1 (13)	5 (23)	11 (16)
		Day 6 n (%)	0 (0)	1 (13)	1 (13)	2 (9)	3 (4)
		Day 7 n (%)	0 (0)	1 (13)	0 (0)	1 (5)	1 (1)
	Tenderness	Any n	8	8	9	25	77
		Day 0 n (%)	5 (63)	7 (88)	9 (100)	21 (84)	69 (90)
		Day 1 n (%)	5 (63)	5 (63)	9 (100)	19 (76)	62 (81)
		Day 2 n (%)	4 (50)	5 (63)	6 (67)	15 (60)	47 (61)
		Day 3 n (%)	3 (38)	3 (38)	2 (22)	8 (32)	27 (35)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 8 of 10)

Table 14.3.1-1.6.2-1: Frequency of subjects with solicited local reactions by term per day - BNT162b1

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=29)	Total (N=120)
After boost	Tenderness	Day 4 n (%)	3 (38)	2 (25)	1 (11)	6 (24)	18 (23)
		Day 5 n (%)	3 (38)	2 (25)	1 (11)	6 (24)	14 (18)
		Day 6 n (%)	2 (25)	1 (13)	1 (11)	4 (16)	8 (10)
		Day 7 n (%)	0 (0)	1 (13)	0 (0)	1 (4)	2 (3)
	Erythema/Redness	Any n	2	0	2	4	7
		Day 1 n (%)	1 (50)	0 (0)	0 (0)	1 (25)	1 (14)
		Day 2 n (%)	1 (50)	0 (0)	2 (100)	3 (75)	5 (71)
		Day 3 n (%)	1 (50)	0 (0)	1 (50)	2 (50)	4 (57)
		Day 4 n (%)	2 (100)	0 (0)	1 (50)	3 (75)	4 (57)
		Day 5 n (%)	2 (100)	0 (0)	0 (0)	2 (50)	3 (43)
		Day 6 n (%)	1 (50)	0 (0)	0 (0)	1 (25)	1 (14)
	Induration/Swelling	Any n	2	3	2	7	13
		Day 0 n (%)	1 (50)	1 (33)	0 (0)	2 (29)	4 (31)
		Day 1 n (%)	2 (100)	2 (67)	0 (0)	4 (57)	9 (69)
		Day 2 n (%)	1 (50)	1 (33)	1 (50)	3 (43)	3 (23)
		Day 3 n (%)	1 (50)	0 (0)	1 (50)	2 (29)	2 (15)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 9 of 10)

Table 14.3.1-1.6.2-1: Frequency of subjects with solicited local reactions by term per day - BNT162b1

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=29)	Total (N=120)
After boost	Induration/Swelling	Day 4 n (%)	1 (50)	0 (0)	1 (50)	2 (29)	2 (15)
		Day 5 n (%)	1 (50)	0 (0)	1 (50)	2 (29)	3 (23)
		Day 6 n (%)	1 (50)	0 (0)	1 (50)	2 (29)	2 (15)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 10 of 10)

14.3.1-2 Systemic reactions

Table 14.3.1-2.1-1: Summary of solicited systemic reactions - BNT162b1

Safety set

		Younger dose ranging cohorts							
Time interval		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Prime up to Day 7 after prime	nn	12	12	12	12	12	12	12	84
	Any systemic reaction n (%)	9 (75)	8 (67)	8 (67)	11 (92)	11 (92)	12 (100)	12 (100)	71 (85)
	Any grade >= 3 systemic reaction n (%)	0 (0)	0 (0)	1 (8)	2 (17)	3 (25)	5 (42)	8 (67)	19 (23)
Boost up to Day 7 after boost	nn	12	12	11	11	12	11	N/A	69
	Any systemic reaction n (%)	7 (58)	7 (58)	9 (82)	10 (91)	11 (92)	11 (100)	N/A	55 (80)
	Any grade >= 3 systemic reaction n (%)	3 (25)	1 (8)	5 (45)	5 (45)	6 (50)	5 (45)	N/A	25 (36)
Combined interval	nn	12	12	12	12	12	12	12	84
	Any systemic reaction n (%)	11 (92)	9 (75)	10 (83)	11 (92)	12 (100)	12 (100)	12 (100)	77 (92)
	Any grade >= 3 systemic reaction n (%)	3 (25)	1 (8)	6 (50)	5 (42)	6 (50)	8 (67)	8 (67)	37 (44)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reactions; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_1-2.sas (Page 1 of 2)

Table 14.3.1-2.1-1: Summary of solicited systemic reactions - BNT162b1

Safety set

		Older dose ranging cohorts				
Time interval		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Prime up to Day 7 after prime	nn	12	12	12	36	120
	Any systemic reaction n (%)	9 (75)	11 (92)	11 (92)	31 (86)	102 (85)
	Any grade >= 3 systemic reaction n (%)	1 (8)	1 (8)	2 (17)	4 (11)	23 (19)
Boost up to Day 7 after boost	nn	12	11	12	35	104
	Any systemic reaction n (%)	8 (67)	10 (91)	12 (100)	30 (86)	85 (82)
	Any grade >= 3 systemic reaction n (%)	2 (17)	2 (18)	4 (33)	8 (23)	33 (32)
Combined interval	nn	12	12	12	36	120
	Any systemic reaction n (%)	9 (75)	12 (100)	12 (100)	33 (92)	110 (92)
	Any grade >= 3 systemic reaction n (%)	2 (17)	3 (25)	5 (42)	10 (28)	47 (39)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reactions; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_1-2.sas (Page 2 of 2)

Table 14.3.1-2.2-1: Summary of solicited systemic reactions - completers only - BNT162b1

Safety set

		Younger dose ranging cohorts							
Time interval		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=11)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=83)
Prime up to Day 7 after prime	nn	12	12	12	11	12	12	12	83
	Any systemic reaction n (%)	9 (75)	8 (67)	8 (67)	11 (100)	11 (92)	12 (100)	12 (100)	71 (86)
	Any grade >= 3 systemic reaction n (%)	0 (0)	0 (0)	1 (8)	2 (18)	3 (25)	5 (42)	8 (67)	19 (23)
Boost up to Day 7 after boost	nn	12	12	11	11	12	11	N/A	69
	Any systemic reaction n (%)	7 (58)	7 (58)	9 (82)	10 (91)	11 (92)	11 (100)	N/A	55 (80)
	Any grade >= 3 systemic reaction n (%)	3 (25)	1 (8)	5 (45)	5 (45)	6 (50)	5 (45)	N/A	25 (36)
Combined interval	nn	12	12	11	11	12	11	N/A	69
	Any systemic reaction n (%)	11 (92)	9 (75)	9 (82)	11 (100)	12 (100)	11 (100)	N/A	63 (91)
	Any grade >= 3 systemic reaction n (%)	3 (25)	1 (8)	5 (45)	5 (45)	6 (50)	8 (73)	N/A	28 (41)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reactions; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

Program: Tsaf_sysR_1-2.sas (Page 1 of 2)

Table 14.3.1-2.2-1: Summary of solicited systemic reactions - completers only - BNT162b1

Safety set

		Older dose ranging cohorts				
Time interval		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=119)
Prime up to Day 7 after prime	nn	12	12	12	36	119
	Any systemic reaction n (%)	9 (75)	11 (92)	11 (92)	31 (86)	102 (86)
	Any grade >= 3 systemic reaction n (%)	1 (8)	1 (8)	2 (17)	4 (11)	23 (19)
Boost up to Day 7 after boost	nn	12	11	12	35	104
	Any systemic reaction n (%)	8 (67)	10 (91)	12 (100)	30 (86)	85 (82)
	Any grade >= 3 systemic reaction n (%)	2 (17)	2 (18)	4 (33)	8 (23)	33 (32)
Combined interval	nn	12	11	12	35	104
	Any systemic reaction n (%)	9 (75)	11 (100)	12 (100)	32 (91)	95 (91)
	Any grade >= 3 systemic reaction n (%)	2 (17)	3 (27)	5 (42)	10 (29)	38 (37)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reactions; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

Program: Tsaf_sysR_1-2.sas (Page 2 of 2)

Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Prime up to Day 7 after prime		nn	12	12	12	12	12	12	12	84
	Any	Any n (%)	9 (75)	8 (67)	8 (67)	11 (92)	11 (92)	12 (100)	12 (100)	71 (85)
		Mild n (%)	9 (75)	8 (67)	8 (67)	11 (92)	11 (92)	12 (100)	12 (100)	71 (85)
		Moderate n (%)	3 (25)	4 (33)	3 (25)	4 (33)	5 (42)	10 (83)	9 (75)	38 (45)
		Severe n (%)	0 (0)	0 (0)	1 (8)	2 (17)	3 (25)	5 (42)	8 (67)	19 (23)
	Nausea	Any n (%)	1 (8)	0 (0)	1 (8)	4 (33)	1 (8)	4 (33)	4 (33)	15 (18)
		Mild n (%)	1 (8)	0 (0)	1 (8)	4 (33)	0 (0)	4 (33)	3 (25)	13 (15)
		Moderate n (%)	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	3 (25)	1 (8)	7 (8)
		Severe n (%)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
	Vomiting	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
		Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
	Diarrhea	Any n (%)	1 (8)	1 (8)	2 (17)	0 (0)	1 (8)	1 (8)	1 (8)	7 (8)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_3-4.sas (Page 1 of 22)

Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Prime up to Day 7 after prime	Diarrhea	Mild n (%)	1 (8)	1 (8)	2 (17)	0 (0)	1 (8)	1 (8)	1 (8)	7 (8)
		Moderate n (%)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Headache	Any n (%)	5 (42)	6 (50)	5 (42)	6 (50)	10 (83)	10 (83)	8 (67)	50 (60)
		Mild n (%)	4 (33)	6 (50)	5 (42)	5 (42)	8 (67)	7 (58)	7 (58)	42 (50)
		Moderate n (%)	2 (17)	0 (0)	3 (25)	3 (25)	5 (42)	6 (50)	3 (25)	22 (26)
		Severe n (%)	0 (0)	0 (0)	1 (8)	2 (17)	1 (8)	2 (17)	3 (25)	9 (11)
	Fatigue	Any n (%)	8 (67)	6 (50)	6 (50)	11 (92)	8 (67)	12 (100)	11 (92)	62 (74)
		Mild n (%)	8 (67)	5 (42)	6 (50)	10 (83)	7 (58)	10 (83)	9 (75)	55 (65)
		Moderate n (%)	0 (0)	4 (33)	2 (17)	3 (25)	3 (25)	7 (58)	3 (25)	22 (26)
		Severe n (%)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (17)	2 (17)	6 (7)
	Myalgia	Any n (%)	1 (8)	0 (0)	2 (17)	6 (50)	6 (50)	7 (58)	11 (92)	33 (39)
		Mild n (%)	1 (8)	0 (0)	2 (17)	6 (50)	3 (25)	6 (50)	10 (83)	28 (33)
		Moderate n (%)	0 (0)	0 (0)	1 (8)	1 (8)	4 (33)	3 (25)	5 (42)	14 (17)
		Severe n (%)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	2 (17)	0 (0)	5 (6)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_3-4.sas (Page 2 of 22)

Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Prime up to Day 7 after prime	Arthralgia	Any n (%)	0 (0)	0 (0)	1 (8)	3 (25)	4 (33)	5 (42)	5 (42)	18 (21)
		Mild n (%)	0 (0)	0 (0)	1 (8)	3 (25)	2 (17)	3 (25)	4 (33)	13 (15)
		Moderate n (%)	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	2 (17)	2 (17)	7 (8)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	1 (8)	1 (8)	4 (5)
	Chills	Any n (%)	2 (17)	1 (8)	1 (8)	4 (33)	4 (33)	10 (83)	10 (83)	32 (38)
		Mild n (%)	2 (17)	1 (8)	1 (8)	4 (33)	1 (8)	5 (42)	8 (67)	22 (26)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	2 (17)	1 (8)	3 (25)	2 (17)	8 (10)
		Severe n (%)	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	3 (25)	2 (17)	8 (10)
	Loss of Appetite	Any n (%)	0 (0)	0 (0)	2 (17)	3 (25)	3 (25)	7 (58)	6 (50)	21 (25)
		Mild n (%)	0 (0)	0 (0)	2 (17)	3 (25)	3 (25)	7 (58)	5 (42)	20 (24)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	0 (0)	3 (4)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
	Malaise	Any n (%)	2 (17)	0 (0)	2 (17)	6 (50)	8 (67)	10 (83)	9 (75)	37 (44)
		Mild n (%)	1 (8)	0 (0)	2 (17)	6 (50)	8 (67)	8 (67)	8 (67)	33 (39)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_3-4.sas (Page 3 of 22)

Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Prime up to Day 7 after prime	Malaise	Moderate n (%)	1 (8)	0 (0)	1 (8)	2 (17)	0 (0)	7 (58)	3 (25)	14 (17)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	2 (17)	3 (25)	7 (8)
	Fever	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	4 (33)	4 (33)	9 (11)
		Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	3 (25)	5 (6)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	1 (8)	4 (5)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Boost up to Day 7 after boost		nn	12	12	11	11	12	11	N/A	69
	Any	Any n (%)	7 (58)	7 (58)	9 (82)	10 (91)	11 (92)	11 (100)	N/A	55 (80)
		Mild n (%)	4 (33)	6 (50)	9 (82)	9 (82)	10 (83)	11 (100)	N/A	49 (71)
		Moderate n (%)	7 (58)	5 (42)	6 (55)	8 (73)	9 (75)	11 (100)	N/A	46 (67)
		Severe n (%)	3 (25)	1 (8)	5 (45)	5 (45)	6 (50)	5 (45)	N/A	25 (36)
	Nausea	Any n (%)	2 (17)	1 (8)	3 (27)	3 (27)	3 (25)	4 (36)	N/A	16 (23)
		Mild n (%)	1 (8)	1 (8)	2 (18)	3 (27)	2 (17)	4 (36)	N/A	13 (19)
		Moderate n (%)	1 (8)	0 (0)	1 (9)	1 (9)	1 (8)	2 (18)	N/A	6 (9)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_3-4.sas (Page 4 of 22)

Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Boost up to Day 7 after boost	Nausea	Severe n (%)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	N/A	2 (3)
	Vomiting	Any n (%)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (9)	N/A	2 (3)
		Mild n (%)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	N/A	1 (1)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (9)	N/A	2 (3)
	Diarrhea	Any n (%)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (9)	N/A	2 (3)
		Mild n (%)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (9)	N/A	2 (3)
		Severe n (%)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	N/A	1 (1)
	Headache	Any n (%)	7 (58)	6 (50)	8 (73)	9 (82)	10 (83)	9 (82)	N/A	49 (71)
		Mild n (%)	4 (33)	4 (33)	8 (73)	7 (64)	7 (58)	5 (45)	N/A	35 (51)
		Moderate n (%)	5 (42)	5 (42)	3 (27)	7 (64)	5 (42)	4 (36)	N/A	29 (42)
		Severe n (%)	0 (0)	0 (0)	1 (9)	3 (27)	5 (42)	4 (36)	N/A	13 (19)
	Fatigue	Any n (%)	5 (42)	6 (50)	6 (55)	6 (55)	10 (83)	9 (82)	N/A	42 (61)
		Mild n (%)	3 (25)	6 (50)	6 (55)	6 (55)	7 (58)	9 (82)	N/A	37 (54)
		Moderate n (%)	5 (42)	3 (25)	4 (36)	3 (27)	6 (50)	6 (55)	N/A	27 (39)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Boost up to Day 7 after boost	Fatigue	Severe n (%)	1 (8)	1 (8)	0 (0)	1 (9)	3 (25)	3 (27)	N/A	9 (13)
	Myalgia	Any n (%)	5 (42)	2 (17)	6 (55)	5 (45)	9 (75)	6 (55)	N/A	33 (48)
		Mild n (%)	3 (25)	2 (17)	6 (55)	5 (45)	6 (50)	5 (45)	N/A	27 (39)
		Moderate n (%)	3 (25)	0 (0)	2 (18)	3 (27)	7 (58)	5 (45)	N/A	20 (29)
		Severe n (%)	0 (0)	0 (0)	1 (9)	1 (9)	3 (25)	0 (0)	N/A	5 (7)
	Arthralgia	Any n (%)	2 (17)	1 (8)	3 (27)	1 (9)	8 (67)	6 (55)	N/A	21 (30)
		Mild n (%)	2 (17)	0 (0)	2 (18)	1 (9)	6 (50)	5 (45)	N/A	16 (23)
		Moderate n (%)	1 (8)	1 (8)	1 (9)	0 (0)	4 (33)	4 (36)	N/A	11 (16)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	0 (0)	N/A	3 (4)
	Chills	Any n (%)	4 (33)	1 (8)	5 (45)	5 (45)	9 (75)	9 (82)	N/A	33 (48)
		Mild n (%)	3 (25)	1 (8)	4 (36)	4 (36)	5 (42)	4 (36)	N/A	21 (30)
		Moderate n (%)	1 (8)	0 (0)	1 (9)	1 (9)	3 (25)	5 (45)	N/A	11 (16)
		Severe n (%)	0 (0)	0 (0)	2 (18)	3 (27)	4 (33)	3 (27)	N/A	12 (17)
	Loss of Appetite	Any n (%)	2 (17)	1 (8)	6 (55)	4 (36)	5 (42)	8 (73)	N/A	26 (38)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_3-4.sas (Page 6 of 22)

Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Boost up to Day 7 after boost	Loss of Appetite	Mild n (%)	1 (8)	1 (8)	5 (45)	3 (27)	2 (17)	5 (45)	N/A	17 (25)
		Moderate n (%)	1 (8)	0 (0)	1 (9)	3 (27)	2 (17)	6 (55)	N/A	13 (19)
		Severe n (%)	1 (8)	0 (0)	1 (9)	1 (9)	1 (8)	4 (36)	N/A	8 (12)
	Malaise	Any n (%)	2 (17)	2 (17)	6 (55)	5 (45)	10 (83)	10 (91)	N/A	35 (51)
		Mild n (%)	2 (17)	2 (17)	6 (55)	5 (45)	7 (58)	8 (73)	N/A	30 (43)
		Moderate n (%)	2 (17)	2 (17)	1 (9)	2 (18)	5 (42)	4 (36)	N/A	16 (23)
		Severe n (%)	0 (0)	0 (0)	1 (9)	1 (9)	5 (42)	4 (36)	N/A	11 (16)
	Fever	Any n (%)	1 (8)	1 (8)	4 (36)	4 (36)	5 (42)	6 (55)	N/A	21 (30)
		Mild n (%)	0 (0)	0 (0)	3 (27)	0 (0)	4 (33)	4 (36)	N/A	11 (16)
		Moderate n (%)	0 (0)	1 (8)	1 (9)	3 (27)	0 (0)	4 (36)	N/A	9 (13)
		Severe n (%)	1 (8)	0 (0)	1 (9)	2 (18)	1 (8)	2 (18)	N/A	7 (10)
Combined interval		nn	12	12	12	12	12	12	12	84
	Any	Any n (%)	11 (92)	9 (75)	10 (83)	11 (92)	12 (100)	12 (100)	12 (100)	77 (92)
		Mild n (%)	10 (83)	9 (75)	10 (83)	11 (92)	12 (100)	12 (100)	12 (100)	76 (90)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_3-4.sas (Page 7 of 22)

Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Combined interval	Any	Moderate n (%)	7 (58)	8 (67)	7 (58)	9 (75)	10 (83)	12 (100)	9 (75)	62 (74)
		Severe n (%)	3 (25)	1 (8)	6 (50)	5 (42)	6 (50)	8 (67)	8 (67)	37 (44)
	Nausea	Any n (%)	2 (17)	1 (8)	4 (33)	5 (42)	4 (33)	5 (42)	4 (33)	25 (30)
		Mild n (%)	2 (17)	1 (8)	3 (25)	5 (42)	2 (17)	5 (42)	3 (25)	21 (25)
		Moderate n (%)	1 (8)	0 (0)	2 (17)	2 (17)	2 (17)	3 (25)	1 (8)	11 (13)
		Severe n (%)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
	Vomiting	Any n (%)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	3 (4)
		Mild n (%)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	2 (2)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	2 (2)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
	Diarrhea	Any n (%)	1 (8)	1 (8)	2 (17)	1 (8)	1 (8)	2 (17)	1 (8)	9 (11)
		Mild n (%)	1 (8)	1 (8)	2 (17)	1 (8)	1 (8)	2 (17)	1 (8)	9 (11)
		Moderate n (%)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Severe n (%)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Combined interval	Headache	Any n (%)	8 (67)	9 (75)	10 (83)	9 (75)	10 (83)	12 (100)	8 (67)	66 (79)
		Mild n (%)	7 (58)	8 (67)	10 (83)	8 (67)	9 (75)	10 (83)	7 (58)	59 (70)
		Moderate n (%)	5 (42)	5 (42)	4 (33)	8 (67)	9 (75)	8 (67)	3 (25)	42 (50)
		Severe n (%)	0 (0)	0 (0)	2 (17)	4 (33)	5 (42)	6 (50)	3 (25)	20 (24)
	Fatigue	Any n (%)	10 (83)	7 (58)	7 (58)	11 (92)	10 (83)	12 (100)	11 (92)	68 (81)
		Mild n (%)	8 (67)	6 (50)	7 (58)	11 (92)	9 (75)	11 (92)	9 (75)	61 (73)
		Moderate n (%)	5 (42)	6 (50)	5 (42)	4 (33)	8 (67)	9 (75)	3 (25)	40 (48)
		Severe n (%)	1 (8)	1 (8)	1 (8)	1 (8)	3 (25)	4 (33)	2 (17)	13 (15)
	Myalgia	Any n (%)	5 (42)	2 (17)	7 (58)	7 (58)	10 (83)	9 (75)	11 (92)	51 (61)
		Mild n (%)	3 (25)	2 (17)	7 (58)	7 (58)	7 (58)	7 (58)	10 (83)	43 (51)
		Moderate n (%)	3 (25)	0 (0)	3 (25)	3 (25)	8 (67)	6 (50)	5 (42)	28 (33)
		Severe n (%)	0 (0)	0 (0)	1 (8)	1 (8)	3 (25)	2 (17)	0 (0)	7 (8)
	Arthralgia	Any n (%)	2 (17)	1 (8)	4 (33)	3 (25)	8 (67)	6 (50)	5 (42)	29 (35)
		Mild n (%)	2 (17)	0 (0)	3 (25)	3 (25)	6 (50)	5 (42)	4 (33)	23 (27)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Combined interval	Arthralgia	Moderate n (%)	1 (8)	1 (8)	2 (17)	0 (0)	6 (50)	4 (33)	2 (17)	16 (19)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	1 (8)	1 (8)	5 (6)
	Chills	Any n (%)	4 (33)	1 (8)	6 (50)	6 (50)	9 (75)	11 (92)	10 (83)	47 (56)
		Mild n (%)	3 (25)	1 (8)	5 (42)	5 (42)	5 (42)	8 (67)	8 (67)	35 (42)
		Moderate n (%)	1 (8)	0 (0)	1 (8)	3 (25)	3 (25)	7 (58)	2 (17)	17 (20)
		Severe n (%)	0 (0)	0 (0)	3 (25)	3 (25)	4 (33)	5 (42)	2 (17)	17 (20)
	Loss of Appetite	Any n (%)	2 (17)	1 (8)	7 (58)	5 (42)	6 (50)	10 (83)	6 (50)	37 (44)
		Mild n (%)	1 (8)	1 (8)	6 (50)	5 (42)	4 (33)	8 (67)	5 (42)	30 (36)
		Moderate n (%)	1 (8)	0 (0)	1 (8)	3 (25)	2 (17)	7 (58)	0 (0)	14 (17)
		Severe n (%)	1 (8)	0 (0)	1 (8)	1 (8)	1 (8)	4 (33)	1 (8)	9 (11)
	Malaise	Any n (%)	2 (17)	2 (17)	7 (58)	8 (67)	10 (83)	12 (100)	9 (75)	50 (60)
		Mild n (%)	2 (17)	2 (17)	7 (58)	8 (67)	9 (75)	12 (100)	8 (67)	48 (57)
		Moderate n (%)	2 (17)	2 (17)	2 (17)	4 (33)	5 (42)	9 (75)	3 (25)	27 (32)
		Severe n (%)	0 (0)	0 (0)	1 (8)	1 (8)	5 (42)	5 (42)	3 (25)	15 (18)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Combined interval	Fever	Any n (%)	1 (8)	1 (8)	4 (33)	4 (33)	5 (42)	7 (58)	4 (33)	26 (31)
		Mild n (%)	0 (0)	0 (0)	3 (25)	0 (0)	4 (33)	5 (42)	3 (25)	15 (18)
		Moderate n (%)	0 (0)	1 (8)	1 (8)	3 (25)	1 (8)	4 (33)	1 (8)	11 (13)
		Severe n (%)	1 (8)	0 (0)	1 (8)	2 (17)	1 (8)	2 (17)	1 (8)	8 (10)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Prime up to Day 7 after prime		nn	12	12	12	36	120
	Any	Any n (%)	9 (75)	11 (92)	11 (92)	31 (86)	102 (85)
		Mild n (%)	8 (67)	11 (92)	11 (92)	30 (83)	101 (84)
		Moderate n (%)	5 (42)	6 (50)	4 (33)	15 (42)	53 (44)
		Severe n (%)	1 (8)	1 (8)	2 (17)	4 (11)	23 (19)
	Nausea	Any n (%)	1 (8)	1 (8)	2 (17)	4 (11)	19 (16)
		Mild n (%)	0 (0)	0 (0)	1 (8)	1 (3)	14 (12)
		Moderate n (%)	1 (8)	1 (8)	1 (8)	3 (8)	10 (8)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Vomiting	Any n (%)	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
		Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Moderate n (%)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Diarrhea	Any n (%)	0 (0)	2 (17)	1 (8)	3 (8)	10 (8)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Prime up to Day 7 after prime	Diarrhea	Mild n (%)	0 (0)	2 (17)	1 (8)	3 (8)	10 (8)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Headache	Any n (%)	8 (67)	6 (50)	4 (33)	18 (50)	68 (57)
		Mild n (%)	6 (50)	2 (17)	3 (25)	11 (31)	53 (44)
		Moderate n (%)	4 (33)	5 (42)	2 (17)	11 (31)	33 (28)
		Severe n (%)	1 (8)	0 (0)	2 (17)	3 (8)	12 (10)
	Fatigue	Any n (%)	6 (50)	7 (58)	9 (75)	22 (61)	84 (70)
		Mild n (%)	5 (42)	6 (50)	7 (58)	18 (50)	73 (61)
		Moderate n (%)	0 (0)	1 (8)	2 (17)	3 (8)	25 (21)
		Severe n (%)	1 (8)	1 (8)	1 (8)	3 (8)	9 (8)
	Myalgia	Any n (%)	2 (17)	5 (42)	7 (58)	14 (39)	47 (39)
		Mild n (%)	1 (8)	5 (42)	6 (50)	12 (33)	40 (33)
		Moderate n (%)	1 (8)	1 (8)	2 (17)	4 (11)	18 (15)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Prime up to Day 7 after prime	Arthralgia	Any n (%)	1 (8)	3 (25)	4 (33)	8 (22)	26 (22)
		Mild n (%)	0 (0)	3 (25)	4 (33)	7 (19)	20 (17)
		Moderate n (%)	1 (8)	1 (8)	1 (8)	3 (8)	10 (8)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
	Chills	Any n (%)	1 (8)	3 (25)	3 (25)	7 (19)	39 (33)
		Mild n (%)	0 (0)	1 (8)	3 (25)	4 (11)	26 (22)
		Moderate n (%)	1 (8)	2 (17)	0 (0)	3 (8)	11 (9)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	8 (7)
	Loss of Appetite	Any n (%)	1 (8)	0 (0)	2 (17)	3 (8)	24 (20)
		Mild n (%)	1 (8)	0 (0)	1 (8)	2 (6)	22 (18)
		Moderate n (%)	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Malaise	Any n (%)	3 (25)	1 (8)	4 (33)	8 (22)	45 (38)
		Mild n (%)	2 (17)	0 (0)	4 (33)	6 (17)	39 (33)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_3-4.sas (Page 14 of 22)

Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Prime up to Day 7 after prime	Malaise	Moderate n (%)	0 (0)	1 (8)	0 (0)	1 (3)	15 (13)
		Severe n (%)	1 (8)	0 (0)	1 (8)	2 (6)	9 (8)
	Fever	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	9 (8)
		Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Boost up to Day 7 after boost		nn	12	11	12	35	104
	Any	Any n (%)	8 (67)	10 (91)	12 (100)	30 (86)	85 (82)
		Mild n (%)	8 (67)	9 (82)	12 (100)	29 (83)	78 (75)
		Moderate n (%)	2 (17)	6 (55)	7 (58)	15 (43)	61 (59)
		Severe n (%)	2 (17)	2 (18)	4 (33)	8 (23)	33 (32)
	Nausea	Any n (%)	1 (8)	2 (18)	4 (33)	7 (20)	23 (22)
		Mild n (%)	1 (8)	2 (18)	3 (25)	6 (17)	19 (18)
		Moderate n (%)	0 (0)	0 (0)	2 (17)	2 (6)	8 (8)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Boost up to Day 7 after boost	Nausea	Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Vomiting	Any n (%)	1 (8)	0 (0)	1 (8)	2 (6)	4 (4)
		Mild n (%)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
		Moderate n (%)	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
	Diarrhea	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Headache	Any n (%)	8 (67)	9 (82)	10 (83)	27 (77)	76 (73)
		Mild n (%)	7 (58)	6 (55)	8 (67)	21 (60)	56 (54)
		Moderate n (%)	1 (8)	4 (36)	4 (33)	9 (26)	38 (37)
		Severe n (%)	2 (17)	0 (0)	0 (0)	2 (6)	15 (14)
	Fatigue	Any n (%)	4 (33)	7 (64)	12 (100)	23 (66)	65 (63)
		Mild n (%)	3 (25)	7 (64)	11 (92)	21 (60)	58 (56)
		Moderate n (%)	1 (8)	0 (0)	4 (33)	5 (14)	32 (31)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Boost up to Day 7 after boost	Fatigue	Severe n (%)	0 (0)	0 (0)	3 (25)	3 (9)	12 (12)
	Myalgia	Any n (%)	4 (33)	5 (45)	6 (50)	15 (43)	48 (46)
		Mild n (%)	4 (33)	3 (27)	6 (50)	13 (37)	40 (38)
		Moderate n (%)	1 (8)	4 (36)	2 (17)	7 (20)	27 (26)
		Severe n (%)	0 (0)	1 (9)	1 (8)	2 (6)	7 (7)
	Arthralgia	Any n (%)	3 (25)	5 (45)	5 (42)	13 (37)	34 (33)
		Mild n (%)	3 (25)	4 (36)	5 (42)	12 (34)	28 (27)
		Moderate n (%)	0 (0)	3 (27)	0 (0)	3 (9)	14 (13)
		Severe n (%)	0 (0)	1 (9)	1 (8)	2 (6)	5 (5)
	Chills	Any n (%)	3 (25)	5 (45)	6 (50)	14 (40)	47 (45)
		Mild n (%)	3 (25)	3 (27)	4 (33)	10 (29)	31 (30)
		Moderate n (%)	0 (0)	3 (27)	4 (33)	7 (20)	18 (17)
		Severe n (%)	1 (8)	1 (9)	1 (8)	3 (9)	15 (14)
	Loss of Appetite	Any n (%)	1 (8)	3 (27)	6 (50)	10 (29)	36 (35)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Boost up to Day 7 after boost	Loss of Appetite	Mild n (%)	1 (8)	2 (18)	5 (42)	8 (23)	25 (24)
		Moderate n (%)	0 (0)	1 (9)	1 (8)	2 (6)	15 (14)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	8 (8)
	Malaise	Any n (%)	4 (33)	6 (55)	6 (50)	16 (46)	51 (49)
		Mild n (%)	4 (33)	6 (55)	6 (50)	16 (46)	46 (44)
		Moderate n (%)	0 (0)	2 (18)	3 (25)	5 (14)	21 (20)
		Severe n (%)	1 (8)	0 (0)	0 (0)	1 (3)	12 (12)
	Fever	Any n (%)	2 (17)	1 (9)	4 (33)	7 (20)	28 (27)
		Mild n (%)	2 (17)	1 (9)	2 (17)	5 (14)	16 (15)
		Moderate n (%)	1 (8)	0 (0)	2 (17)	3 (9)	12 (12)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
Combined interval		nn	12	12	12	36	120
	Any	Any n (%)	9 (75)	12 (100)	12 (100)	33 (92)	110 (92)
		Mild n (%)	8 (67)	12 (100)	12 (100)	32 (89)	108 (90)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Combined interval	Any	Moderate n (%)	6 (50)	9 (75)	7 (58)	22 (61)	84 (70)
		Severe n (%)	2 (17)	3 (25)	5 (42)	10 (28)	47 (39)
	Nausea	Any n (%)	2 (17)	2 (17)	4 (33)	8 (22)	33 (28)
		Mild n (%)	1 (8)	2 (17)	3 (25)	6 (17)	27 (23)
		Moderate n (%)	1 (8)	1 (8)	2 (17)	4 (11)	15 (13)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
	Vomiting	Any n (%)	2 (17)	0 (0)	1 (8)	3 (8)	6 (5)
		Mild n (%)	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
		Moderate n (%)	1 (8)	0 (0)	1 (8)	2 (6)	4 (3)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Diarrhea	Any n (%)	0 (0)	2 (17)	1 (8)	3 (8)	12 (10)
		Mild n (%)	0 (0)	2 (17)	1 (8)	3 (8)	12 (10)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Combined interval	Headache	Any n (%)	9 (75)	10 (83)	10 (83)	29 (81)	95 (79)
		Mild n (%)	7 (58)	7 (58)	10 (83)	24 (67)	83 (69)
		Moderate n (%)	5 (42)	7 (58)	4 (33)	16 (44)	58 (48)
		Severe n (%)	2 (17)	0 (0)	2 (17)	4 (11)	24 (20)
	Fatigue	Any n (%)	7 (58)	8 (67)	12 (100)	27 (75)	95 (79)
		Mild n (%)	5 (42)	8 (67)	11 (92)	24 (67)	85 (71)
		Moderate n (%)	1 (8)	1 (8)	5 (42)	7 (19)	47 (39)
		Severe n (%)	1 (8)	1 (8)	3 (25)	5 (14)	18 (15)
	Myalgia	Any n (%)	4 (33)	6 (50)	8 (67)	18 (50)	69 (58)
		Mild n (%)	4 (33)	5 (42)	8 (67)	17 (47)	60 (50)
		Moderate n (%)	2 (17)	4 (33)	3 (25)	9 (25)	37 (31)
		Severe n (%)	0 (0)	1 (8)	1 (8)	2 (6)	9 (8)
	Arthralgia	Any n (%)	3 (25)	6 (50)	6 (50)	15 (42)	44 (37)
		Mild n (%)	3 (25)	5 (42)	6 (50)	14 (39)	37 (31)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Combined interval	Arthralgia	Moderate n (%)	1 (8)	3 (25)	1 (8)	5 (14)	21 (18)
		Severe n (%)	0 (0)	1 (8)	1 (8)	2 (6)	7 (6)
	Chills	Any n (%)	3 (25)	7 (58)	7 (58)	17 (47)	64 (53)
		Mild n (%)	3 (25)	4 (33)	5 (42)	12 (33)	47 (39)
		Moderate n (%)	1 (8)	4 (33)	4 (33)	9 (25)	26 (22)
		Severe n (%)	1 (8)	1 (8)	1 (8)	3 (8)	20 (17)
	Loss of Appetite	Any n (%)	2 (17)	3 (25)	6 (50)	11 (31)	48 (40)
		Mild n (%)	2 (17)	2 (17)	5 (42)	9 (25)	39 (33)
		Moderate n (%)	0 (0)	1 (8)	2 (17)	3 (8)	17 (14)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	9 (8)
	Malaise	Any n (%)	5 (42)	6 (50)	7 (58)	18 (50)	68 (57)
		Mild n (%)	5 (42)	6 (50)	7 (58)	18 (50)	66 (55)
		Moderate n (%)	0 (0)	3 (25)	3 (25)	6 (17)	33 (28)
		Severe n (%)	1 (8)	0 (0)	1 (8)	2 (6)	17 (14)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.3-1: Frequency of subjects with solicited systemic reactions by grade - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Combined interval	Fever	Any n (%)	2 (17)	1 (8)	4 (33)	7 (19)	33 (28)
		Mild n (%)	2 (17)	1 (8)	2 (17)	5 (14)	20 (17)
		Moderate n (%)	1 (8)	0 (0)	2 (17)	3 (8)	14 (12)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	8 (7)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=11)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=83)
Prime up to Day 7 after prime		nn	12	12	12	11	12	12	12	83
	Any	Any n (%)	9 (75)	8 (67)	8 (67)	11 (100)	11 (92)	12 (100)	12 (100)	71 (86)
		Mild n (%)	9 (75)	8 (67)	8 (67)	11 (100)	11 (92)	12 (100)	12 (100)	71 (86)
		Moderate n (%)	3 (25)	4 (33)	3 (25)	4 (36)	5 (42)	10 (83)	9 (75)	38 (46)
		Severe n (%)	0 (0)	0 (0)	1 (8)	2 (18)	3 (25)	5 (42)	8 (67)	19 (23)
	Nausea	Any n (%)	1 (8)	0 (0)	1 (8)	4 (36)	1 (8)	4 (33)	4 (33)	15 (18)
		Mild n (%)	1 (8)	0 (0)	1 (8)	4 (36)	0 (0)	4 (33)	3 (25)	13 (16)
		Moderate n (%)	0 (0)	0 (0)	1 (8)	1 (9)	1 (8)	3 (25)	1 (8)	7 (8)
		Severe n (%)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
	Vomiting	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
		Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
	Diarrhea	Any n (%)	1 (8)	1 (8)	2 (17)	0 (0)	1 (8)	1 (8)	1 (8)	7 (8)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=11)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=83)
Prime up to Day 7 after prime	Diarrhea	Mild n (%)	1 (8)	1 (8)	2 (17)	0 (0)	1 (8)	1 (8)	1 (8)	7 (8)
		Moderate n (%)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Headache	Any n (%)	5 (42)	6 (50)	5 (42)	6 (55)	10 (83)	10 (83)	8 (67)	50 (60)
		Mild n (%)	4 (33)	6 (50)	5 (42)	5 (45)	8 (67)	7 (58)	7 (58)	42 (51)
		Moderate n (%)	2 (17)	0 (0)	3 (25)	3 (27)	5 (42)	6 (50)	3 (25)	22 (27)
		Severe n (%)	0 (0)	0 (0)	1 (8)	2 (18)	1 (8)	2 (17)	3 (25)	9 (11)
	Fatigue	Any n (%)	8 (67)	6 (50)	6 (50)	11 (100)	8 (67)	12 (100)	11 (92)	62 (75)
		Mild n (%)	8 (67)	5 (42)	6 (50)	10 (91)	7 (58)	10 (83)	9 (75)	55 (66)
		Moderate n (%)	0 (0)	4 (33)	2 (17)	3 (27)	3 (25)	7 (58)	3 (25)	22 (27)
		Severe n (%)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (17)	2 (17)	6 (7)
	Myalgia	Any n (%)	1 (8)	0 (0)	2 (17)	6 (55)	6 (50)	7 (58)	11 (92)	33 (40)
		Mild n (%)	1 (8)	0 (0)	2 (17)	6 (55)	3 (25)	6 (50)	10 (83)	28 (34)
		Moderate n (%)	0 (0)	0 (0)	1 (8)	1 (9)	4 (33)	3 (25)	5 (42)	14 (17)
		Severe n (%)	0 (0)	0 (0)	0 (0)	1 (9)	2 (17)	2 (17)	0 (0)	5 (6)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=11)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=83)
Prime up to Day 7 after prime	Arthralgia	Any n (%)	0 (0)	0 (0)	1 (8)	3 (27)	4 (33)	5 (42)	5 (42)	18 (22)
		Mild n (%)	0 (0)	0 (0)	1 (8)	3 (27)	2 (17)	3 (25)	4 (33)	13 (16)
		Moderate n (%)	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	2 (17)	2 (17)	7 (8)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	1 (8)	1 (8)	4 (5)
	Chills	Any n (%)	2 (17)	1 (8)	1 (8)	4 (36)	4 (33)	10 (83)	10 (83)	32 (39)
		Mild n (%)	2 (17)	1 (8)	1 (8)	4 (36)	1 (8)	5 (42)	8 (67)	22 (27)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	2 (18)	1 (8)	3 (25)	2 (17)	8 (10)
		Severe n (%)	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	3 (25)	2 (17)	8 (10)
	Loss of Appetite	Any n (%)	0 (0)	0 (0)	2 (17)	3 (27)	3 (25)	7 (58)	6 (50)	21 (25)
		Mild n (%)	0 (0)	0 (0)	2 (17)	3 (27)	3 (25)	7 (58)	5 (42)	20 (24)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	2 (17)	0 (0)	3 (4)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
	Malaise	Any n (%)	2 (17)	0 (0)	2 (17)	6 (55)	8 (67)	10 (83)	9 (75)	37 (45)
		Mild n (%)	1 (8)	0 (0)	2 (17)	6 (55)	8 (67)	8 (67)	8 (67)	33 (40)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=11)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=83)
Prime up to Day 7 after prime	Malaise	Moderate n (%)	1 (8)	0 (0)	1 (8)	2 (18)	0 (0)	7 (58)	3 (25)	14 (17)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	2 (17)	3 (25)	7 (8)
	Fever	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	4 (33)	4 (33)	9 (11)
		Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	3 (25)	5 (6)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	1 (8)	4 (5)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Boost up to Day 7 after boost		nn	12	12	11	11	12	11	N/A	69
	Any	Any n (%)	7 (58)	7 (58)	9 (82)	10 (91)	11 (92)	11 (100)	N/A	55 (80)
		Mild n (%)	4 (33)	6 (50)	9 (82)	9 (82)	10 (83)	11 (100)	N/A	49 (71)
		Moderate n (%)	7 (58)	5 (42)	6 (55)	8 (73)	9 (75)	11 (100)	N/A	46 (67)
		Severe n (%)	3 (25)	1 (8)	5 (45)	5 (45)	6 (50)	5 (45)	N/A	25 (36)
	Nausea	Any n (%)	2 (17)	1 (8)	3 (27)	3 (27)	3 (25)	4 (36)	N/A	16 (23)
		Mild n (%)	1 (8)	1 (8)	2 (18)	3 (27)	2 (17)	4 (36)	N/A	13 (19)
		Moderate n (%)	1 (8)	0 (0)	1 (9)	1 (9)	1 (8)	2 (18)	N/A	6 (9)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=11)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=83)
Boost up to Day 7 after boost	Nausea	Severe n (%)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	N/A	2 (3)
	Vomiting	Any n (%)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (9)	N/A	2 (3)
		Mild n (%)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	N/A	1 (1)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (9)	N/A	2 (3)
	Diarrhea	Any n (%)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (9)	N/A	2 (3)
		Mild n (%)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (9)	N/A	2 (3)
		Severe n (%)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	N/A	1 (1)
	Headache	Any n (%)	7 (58)	6 (50)	8 (73)	9 (82)	10 (83)	9 (82)	N/A	49 (71)
		Mild n (%)	4 (33)	4 (33)	8 (73)	7 (64)	7 (58)	5 (45)	N/A	35 (51)
		Moderate n (%)	5 (42)	5 (42)	3 (27)	7 (64)	5 (42)	4 (36)	N/A	29 (42)
		Severe n (%)	0 (0)	0 (0)	1 (9)	3 (27)	5 (42)	4 (36)	N/A	13 (19)
	Fatigue	Any n (%)	5 (42)	6 (50)	6 (55)	6 (55)	10 (83)	9 (82)	N/A	42 (61)
		Mild n (%)	3 (25)	6 (50)	6 (55)	6 (55)	7 (58)	9 (82)	N/A	37 (54)
		Moderate n (%)	5 (42)	3 (25)	4 (36)	3 (27)	6 (50)	6 (55)	N/A	27 (39)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=11)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=83)
Boost up to Day 7 after boost	Fatigue	Severe n (%)	1 (8)	1 (8)	0 (0)	1 (9)	3 (25)	3 (27)	N/A	9 (13)
	Myalgia	Any n (%)	5 (42)	2 (17)	6 (55)	5 (45)	9 (75)	6 (55)	N/A	33 (48)
		Mild n (%)	3 (25)	2 (17)	6 (55)	5 (45)	6 (50)	5 (45)	N/A	27 (39)
		Moderate n (%)	3 (25)	0 (0)	2 (18)	3 (27)	7 (58)	5 (45)	N/A	20 (29)
		Severe n (%)	0 (0)	0 (0)	1 (9)	1 (9)	3 (25)	0 (0)	N/A	5 (7)
	Arthralgia	Any n (%)	2 (17)	1 (8)	3 (27)	1 (9)	8 (67)	6 (55)	N/A	21 (30)
		Mild n (%)	2 (17)	0 (0)	2 (18)	1 (9)	6 (50)	5 (45)	N/A	16 (23)
		Moderate n (%)	1 (8)	1 (8)	1 (9)	0 (0)	4 (33)	4 (36)	N/A	11 (16)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	0 (0)	N/A	3 (4)
	Chills	Any n (%)	4 (33)	1 (8)	5 (45)	5 (45)	9 (75)	9 (82)	N/A	33 (48)
		Mild n (%)	3 (25)	1 (8)	4 (36)	4 (36)	5 (42)	4 (36)	N/A	21 (30)
		Moderate n (%)	1 (8)	0 (0)	1 (9)	1 (9)	3 (25)	5 (45)	N/A	11 (16)
		Severe n (%)	0 (0)	0 (0)	2 (18)	3 (27)	4 (33)	3 (27)	N/A	12 (17)
	Loss of Appetite	Any n (%)	2 (17)	1 (8)	6 (55)	4 (36)	5 (42)	8 (73)	N/A	26 (38)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

Program: Tsaf_sysR_3-4.sas (Page 6 of 22)

Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=11)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=83)
Boost up to Day 7 after boost	Loss of Appetite	Mild n (%)	1 (8)	1 (8)	5 (45)	3 (27)	2 (17)	5 (45)	N/A	17 (25)
		Moderate n (%)	1 (8)	0 (0)	1 (9)	3 (27)	2 (17)	6 (55)	N/A	13 (19)
		Severe n (%)	1 (8)	0 (0)	1 (9)	1 (9)	1 (8)	4 (36)	N/A	8 (12)
	Malaise	Any n (%)	2 (17)	2 (17)	6 (55)	5 (45)	10 (83)	10 (91)	N/A	35 (51)
		Mild n (%)	2 (17)	2 (17)	6 (55)	5 (45)	7 (58)	8 (73)	N/A	30 (43)
		Moderate n (%)	2 (17)	2 (17)	1 (9)	2 (18)	5 (42)	4 (36)	N/A	16 (23)
		Severe n (%)	0 (0)	0 (0)	1 (9)	1 (9)	5 (42)	4 (36)	N/A	11 (16)
	Fever	Any n (%)	1 (8)	1 (8)	4 (36)	4 (36)	5 (42)	6 (55)	N/A	21 (30)
		Mild n (%)	0 (0)	0 (0)	3 (27)	0 (0)	4 (33)	4 (36)	N/A	11 (16)
		Moderate n (%)	0 (0)	1 (8)	1 (9)	3 (27)	0 (0)	4 (36)	N/A	9 (13)
		Severe n (%)	1 (8)	0 (0)	1 (9)	2 (18)	1 (8)	2 (18)	N/A	7 (10)
Combined interval		nn	12	12	11	11	12	11	N/A	69
	Any	Any n (%)	11 (92)	9 (75)	9 (82)	11 (100)	12 (100)	11 (100)	N/A	63 (91)
		Mild n (%)	10 (83)	9 (75)	9 (82)	11 (100)	12 (100)	11 (100)	N/A	62 (90)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

Program: Tsaf_sysR_3-4.sas (Page 7 of 22)

Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=11)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=83)
Combined interval	Any	Moderate n (%)	7 (58)	8 (67)	6 (55)	9 (82)	10 (83)	11 (100)	N/A	51 (74)
		Severe n (%)	3 (25)	1 (8)	5 (45)	5 (45)	6 (50)	8 (73)	N/A	28 (41)
	Nausea	Any n (%)	2 (17)	1 (8)	3 (27)	5 (45)	4 (33)	5 (45)	N/A	20 (29)
		Mild n (%)	2 (17)	1 (8)	2 (18)	5 (45)	2 (17)	5 (45)	N/A	17 (25)
		Moderate n (%)	1 (8)	0 (0)	1 (9)	2 (18)	2 (17)	3 (27)	N/A	9 (13)
		Severe n (%)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	N/A	2 (3)
	Vomiting	Any n (%)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (9)	N/A	2 (3)
		Mild n (%)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (9)	N/A	2 (3)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (9)	N/A	2 (3)
	Diarrhea	Any n (%)	1 (8)	1 (8)	1 (9)	1 (9)	1 (8)	2 (18)	N/A	7 (10)
		Mild n (%)	1 (8)	1 (8)	1 (9)	1 (9)	1 (8)	2 (18)	N/A	7 (10)
		Severe n (%)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	N/A	1 (1)
	Headache	Any n (%)	8 (67)	9 (75)	9 (82)	9 (82)	10 (83)	11 (100)	N/A	56 (81)
		Mild n (%)	7 (58)	8 (67)	9 (82)	8 (73)	9 (75)	9 (82)	N/A	50 (72)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

Program: Tsaf_sysR_3-4.sas (Page 8 of 22)

Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=11)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=83)
Combined interval	Headache	Moderate n (%)	5 (42)	5 (42)	3 (27)	8 (73)	9 (75)	7 (64)	N/A	37 (54)
		Severe n (%)	0 (0)	0 (0)	1 (9)	4 (36)	5 (42)	6 (55)	N/A	16 (23)
	Fatigue	Any n (%)	10 (83)	7 (58)	6 (55)	11 (100)	10 (83)	11 (100)	N/A	55 (80)
		Mild n (%)	8 (67)	6 (50)	6 (55)	11 (100)	9 (75)	10 (91)	N/A	50 (72)
		Moderate n (%)	5 (42)	6 (50)	4 (36)	4 (36)	8 (67)	8 (73)	N/A	35 (51)
		Severe n (%)	1 (8)	1 (8)	0 (0)	1 (9)	3 (25)	4 (36)	N/A	10 (14)
	Myalgia	Any n (%)	5 (42)	2 (17)	6 (55)	7 (64)	10 (83)	8 (73)	N/A	38 (55)
		Mild n (%)	3 (25)	2 (17)	6 (55)	7 (64)	7 (58)	6 (55)	N/A	31 (45)
		Moderate n (%)	3 (25)	0 (0)	2 (18)	3 (27)	8 (67)	6 (55)	N/A	22 (32)
		Severe n (%)	0 (0)	0 (0)	1 (9)	1 (9)	3 (25)	2 (18)	N/A	7 (10)
	Arthralgia	Any n (%)	2 (17)	1 (8)	3 (27)	3 (27)	8 (67)	6 (55)	N/A	23 (33)
		Mild n (%)	2 (17)	0 (0)	2 (18)	3 (27)	6 (50)	5 (45)	N/A	18 (26)
		Moderate n (%)	1 (8)	1 (8)	1 (9)	0 (0)	6 (50)	4 (36)	N/A	13 (19)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	1 (9)	N/A	4 (6)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=11)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=83)
Combined interval	Chills	Any n (%)	4 (33)	1 (8)	5 (45)	6 (55)	9 (75)	10 (91)	N/A	35 (51)
		Mild n (%)	3 (25)	1 (8)	4 (36)	5 (45)	5 (42)	7 (64)	N/A	25 (36)
		Moderate n (%)	1 (8)	0 (0)	1 (9)	3 (27)	3 (25)	7 (64)	N/A	15 (22)
		Severe n (%)	0 (0)	0 (0)	2 (18)	3 (27)	4 (33)	5 (45)	N/A	14 (20)
	Loss of Appetite	Any n (%)	2 (17)	1 (8)	6 (55)	5 (45)	6 (50)	9 (82)	N/A	29 (42)
		Mild n (%)	1 (8)	1 (8)	5 (45)	5 (45)	4 (33)	7 (64)	N/A	23 (33)
		Moderate n (%)	1 (8)	0 (0)	1 (9)	3 (27)	2 (17)	7 (64)	N/A	14 (20)
		Severe n (%)	1 (8)	0 (0)	1 (9)	1 (9)	1 (8)	4 (36)	N/A	8 (12)
	Malaise	Any n (%)	2 (17)	2 (17)	6 (55)	8 (73)	10 (83)	11 (100)	N/A	39 (57)
		Mild n (%)	2 (17)	2 (17)	6 (55)	8 (73)	9 (75)	11 (100)	N/A	38 (55)
		Moderate n (%)	2 (17)	2 (17)	1 (9)	4 (36)	5 (42)	8 (73)	N/A	22 (32)
		Severe n (%)	0 (0)	0 (0)	1 (9)	1 (9)	5 (42)	5 (45)	N/A	12 (17)
	Fever	Any n (%)	1 (8)	1 (8)	4 (36)	4 (36)	5 (42)	7 (64)	N/A	22 (32)
		Mild n (%)	0 (0)	0 (0)	3 (27)	0 (0)	4 (33)	5 (45)	N/A	12 (17)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

Safety set

			Younger dose ranging cohorts							
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=11)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=83)
Combined interval	Fever	Moderate n (%)	0 (0)	1 (8)	1 (9)	3 (27)	1 (8)	4 (36)	N/A	10 (14)
		Severe n (%)	1 (8)	0 (0)	1 (9)	2 (18)	1 (8)	2 (18)	N/A	7 (10)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=119)
Prime up to Day 7 after prime		nn	12	12	12	36	119
	Any	Any n (%)	9 (75)	11 (92)	11 (92)	31 (86)	102 (86)
		Mild n (%)	8 (67)	11 (92)	11 (92)	30 (83)	101 (85)
		Moderate n (%)	5 (42)	6 (50)	4 (33)	15 (42)	53 (45)
		Severe n (%)	1 (8)	1 (8)	2 (17)	4 (11)	23 (19)
	Nausea	Any n (%)	1 (8)	1 (8)	2 (17)	4 (11)	19 (16)
		Mild n (%)	0 (0)	0 (0)	1 (8)	1 (3)	14 (12)
		Moderate n (%)	1 (8)	1 (8)	1 (8)	3 (8)	10 (8)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Vomiting	Any n (%)	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
		Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Moderate n (%)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Diarrhea	Any n (%)	0 (0)	2 (17)	1 (8)	3 (8)	10 (8)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=119)
Prime up to Day 7 after prime	Diarrhea	Mild n (%)	0 (0)	2 (17)	1 (8)	3 (8)	10 (8)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Headache	Any n (%)	8 (67)	6 (50)	4 (33)	18 (50)	68 (57)
		Mild n (%)	6 (50)	2 (17)	3 (25)	11 (31)	53 (45)
		Moderate n (%)	4 (33)	5 (42)	2 (17)	11 (31)	33 (28)
		Severe n (%)	1 (8)	0 (0)	2 (17)	3 (8)	12 (10)
	Fatigue	Any n (%)	6 (50)	7 (58)	9 (75)	22 (61)	84 (71)
		Mild n (%)	5 (42)	6 (50)	7 (58)	18 (50)	73 (61)
		Moderate n (%)	0 (0)	1 (8)	2 (17)	3 (8)	25 (21)
		Severe n (%)	1 (8)	1 (8)	1 (8)	3 (8)	9 (8)
	Myalgia	Any n (%)	2 (17)	5 (42)	7 (58)	14 (39)	47 (39)
		Mild n (%)	1 (8)	5 (42)	6 (50)	12 (33)	40 (34)
		Moderate n (%)	1 (8)	1 (8)	2 (17)	4 (11)	18 (15)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=119)
Prime up to Day 7 after prime	Arthralgia	Any n (%)	1 (8)	3 (25)	4 (33)	8 (22)	26 (22)
		Mild n (%)	0 (0)	3 (25)	4 (33)	7 (19)	20 (17)
		Moderate n (%)	1 (8)	1 (8)	1 (8)	3 (8)	10 (8)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
	Chills	Any n (%)	1 (8)	3 (25)	3 (25)	7 (19)	39 (33)
		Mild n (%)	0 (0)	1 (8)	3 (25)	4 (11)	26 (22)
		Moderate n (%)	1 (8)	2 (17)	0 (0)	3 (8)	11 (9)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	8 (7)
	Loss of Appetite	Any n (%)	1 (8)	0 (0)	2 (17)	3 (8)	24 (20)
		Mild n (%)	1 (8)	0 (0)	1 (8)	2 (6)	22 (18)
		Moderate n (%)	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Malaise	Any n (%)	3 (25)	1 (8)	4 (33)	8 (22)	45 (38)
		Mild n (%)	2 (17)	0 (0)	4 (33)	6 (17)	39 (33)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=119)
Prime up to Day 7 after prime	Malaise	Moderate n (%)	0 (0)	1 (8)	0 (0)	1 (3)	15 (13)
		Severe n (%)	1 (8)	0 (0)	1 (8)	2 (6)	9 (8)
	Fever	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	9 (8)
		Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Boost up to Day 7 after boost		nn	12	11	12	35	104
	Any	Any n (%)	8 (67)	10 (91)	12 (100)	30 (86)	85 (82)
		Mild n (%)	8 (67)	9 (82)	12 (100)	29 (83)	78 (75)
		Moderate n (%)	2 (17)	6 (55)	7 (58)	15 (43)	61 (59)
		Severe n (%)	2 (17)	2 (18)	4 (33)	8 (23)	33 (32)
	Nausea	Any n (%)	1 (8)	2 (18)	4 (33)	7 (20)	23 (22)
		Mild n (%)	1 (8)	2 (18)	3 (25)	6 (17)	19 (18)
		Moderate n (%)	0 (0)	0 (0)	2 (17)	2 (6)	8 (8)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=119)
Boost up to Day 7 after boost	Nausea	Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Vomiting	Any n (%)	1 (8)	0 (0)	1 (8)	2 (6)	4 (4)
		Mild n (%)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
		Moderate n (%)	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
	Diarrhea	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Headache	Any n (%)	8 (67)	9 (82)	10 (83)	27 (77)	76 (73)
		Mild n (%)	7 (58)	6 (55)	8 (67)	21 (60)	56 (54)
		Moderate n (%)	1 (8)	4 (36)	4 (33)	9 (26)	38 (37)
		Severe n (%)	2 (17)	0 (0)	0 (0)	2 (6)	15 (14)
	Fatigue	Any n (%)	4 (33)	7 (64)	12 (100)	23 (66)	65 (63)
		Mild n (%)	3 (25)	7 (64)	11 (92)	21 (60)	58 (56)
		Moderate n (%)	1 (8)	0 (0)	4 (33)	5 (14)	32 (31)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=119)
Boost up to Day 7 after boost	Fatigue	Severe n (%)	0 (0)	0 (0)	3 (25)	3 (9)	12 (12)
	Myalgia	Any n (%)	4 (33)	5 (45)	6 (50)	15 (43)	48 (46)
		Mild n (%)	4 (33)	3 (27)	6 (50)	13 (37)	40 (38)
		Moderate n (%)	1 (8)	4 (36)	2 (17)	7 (20)	27 (26)
		Severe n (%)	0 (0)	1 (9)	1 (8)	2 (6)	7 (7)
	Arthralgia	Any n (%)	3 (25)	5 (45)	5 (42)	13 (37)	34 (33)
		Mild n (%)	3 (25)	4 (36)	5 (42)	12 (34)	28 (27)
		Moderate n (%)	0 (0)	3 (27)	0 (0)	3 (9)	14 (13)
		Severe n (%)	0 (0)	1 (9)	1 (8)	2 (6)	5 (5)
	Chills	Any n (%)	3 (25)	5 (45)	6 (50)	14 (40)	47 (45)
		Mild n (%)	3 (25)	3 (27)	4 (33)	10 (29)	31 (30)
		Moderate n (%)	0 (0)	3 (27)	4 (33)	7 (20)	18 (17)
		Severe n (%)	1 (8)	1 (9)	1 (8)	3 (9)	15 (14)
	Loss of Appetite	Any n (%)	1 (8)	3 (27)	6 (50)	10 (29)	36 (35)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=119)
Boost up to Day 7 after boost	Loss of Appetite	Mild n (%)	1 (8)	2 (18)	5 (42)	8 (23)	25 (24)
		Moderate n (%)	0 (0)	1 (9)	1 (8)	2 (6)	15 (14)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	8 (8)
	Malaise	Any n (%)	4 (33)	6 (55)	6 (50)	16 (46)	51 (49)
		Mild n (%)	4 (33)	6 (55)	6 (50)	16 (46)	46 (44)
		Moderate n (%)	0 (0)	2 (18)	3 (25)	5 (14)	21 (20)
		Severe n (%)	1 (8)	0 (0)	0 (0)	1 (3)	12 (12)
	Fever	Any n (%)	2 (17)	1 (9)	4 (33)	7 (20)	28 (27)
		Mild n (%)	2 (17)	1 (9)	2 (17)	5 (14)	16 (15)
		Moderate n (%)	1 (8)	0 (0)	2 (17)	3 (9)	12 (12)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
Combined interval		nn	12	11	12	35	104
	Any	Any n (%)	9 (75)	11 (100)	12 (100)	32 (91)	95 (91)
		Mild n (%)	8 (67)	11 (100)	12 (100)	31 (89)	93 (89)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=119)
Combined interval	Any	Moderate n (%)	6 (50)	8 (73)	7 (58)	21 (60)	72 (69)
		Severe n (%)	2 (17)	3 (27)	5 (42)	10 (29)	38 (37)
	Nausea	Any n (%)	2 (17)	2 (18)	4 (33)	8 (23)	28 (27)
		Mild n (%)	1 (8)	2 (18)	3 (25)	6 (17)	23 (22)
		Moderate n (%)	1 (8)	1 (9)	2 (17)	4 (11)	13 (13)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Vomiting	Any n (%)	2 (17)	0 (0)	1 (8)	3 (9)	5 (5)
		Mild n (%)	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
		Moderate n (%)	1 (8)	0 (0)	1 (8)	2 (6)	4 (4)
	Diarrhea	Any n (%)	0 (0)	2 (18)	1 (8)	3 (9)	10 (10)
		Mild n (%)	0 (0)	2 (18)	1 (8)	3 (9)	10 (10)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Headache	Any n (%)	9 (75)	9 (82)	10 (83)	28 (80)	84 (81)
		Mild n (%)	7 (58)	7 (64)	10 (83)	24 (69)	74 (71)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=119)
Combined interval	Headache	Moderate n (%)	5 (42)	6 (55)	4 (33)	15 (43)	52 (50)
		Severe n (%)	2 (17)	0 (0)	2 (17)	4 (11)	20 (19)
	Fatigue	Any n (%)	7 (58)	8 (73)	12 (100)	27 (77)	82 (79)
		Mild n (%)	5 (42)	8 (73)	11 (92)	24 (69)	74 (71)
		Moderate n (%)	1 (8)	1 (9)	5 (42)	7 (20)	42 (40)
		Severe n (%)	1 (8)	1 (9)	3 (25)	5 (14)	15 (14)
	Myalgia	Any n (%)	4 (33)	6 (55)	8 (67)	18 (51)	56 (54)
		Mild n (%)	4 (33)	5 (45)	8 (67)	17 (49)	48 (46)
		Moderate n (%)	2 (17)	4 (36)	3 (25)	9 (26)	31 (30)
		Severe n (%)	0 (0)	1 (9)	1 (8)	2 (6)	9 (9)
	Arthralgia	Any n (%)	3 (25)	6 (55)	6 (50)	15 (43)	38 (37)
		Mild n (%)	3 (25)	5 (45)	6 (50)	14 (40)	32 (31)
		Moderate n (%)	1 (8)	3 (27)	1 (8)	5 (14)	18 (17)
		Severe n (%)	0 (0)	1 (9)	1 (8)	2 (6)	6 (6)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=119)
Combined interval	Chills	Any n (%)	3 (25)	6 (55)	7 (58)	16 (46)	51 (49)
		Mild n (%)	3 (25)	3 (27)	5 (42)	11 (31)	36 (35)
		Moderate n (%)	1 (8)	4 (36)	4 (33)	9 (26)	24 (23)
		Severe n (%)	1 (8)	1 (9)	1 (8)	3 (9)	17 (16)
	Loss of Appetite	Any n (%)	2 (17)	3 (27)	6 (50)	11 (31)	40 (38)
		Mild n (%)	2 (17)	2 (18)	5 (42)	9 (26)	32 (31)
		Moderate n (%)	0 (0)	1 (9)	2 (17)	3 (9)	17 (16)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	8 (8)
	Malaise	Any n (%)	5 (42)	6 (55)	7 (58)	18 (51)	57 (55)
		Mild n (%)	5 (42)	6 (55)	7 (58)	18 (51)	56 (54)
		Moderate n (%)	0 (0)	3 (27)	3 (25)	6 (17)	28 (27)
		Severe n (%)	1 (8)	0 (0)	1 (8)	2 (6)	14 (13)
	Fever	Any n (%)	2 (17)	1 (9)	4 (33)	7 (20)	29 (28)
		Mild n (%)	2 (17)	1 (9)	2 (17)	5 (14)	17 (16)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-1: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b1

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=119)
Combined interval	Fever	Moderate n (%)	1 (8)	0 (0)	2 (17)	3 (9)	13 (13)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.5.1-1: Descriptive statistics of time of solicited systemic reactions - BNT162b1

Safety set

			Younger dose ranging cohorts							
			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Time from dose to first systemic reaction [Days]	n	9	8	8	11	11	12	12	71
		Mean (SD)	1.0 (0.0)	2.3 (2.2)	1.3 (0.5)	1.1 (0.3)	1.1 (0.3)	1.2 (0.4)	1.1 (0.3)	1.2 (0.8)
		Min	1	1	1	1	1	1	1	1
		Median	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
		Max	1	7	2	2	2	2	2	7
	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	1	2	3	5	8	19
		Mean (SD)	- (-)	- (-)	2.0 (-)	1.5 (-)	1.0 (0.0)	2.0 (0.0)	1.1 (0.4)	1.4 (0.5)
		Min	-	-	2	1	1	2	1	1
		Median	-	-	2.0	1.5	1.0	2.0	1.0	1.0
		Max	-	-	2	2	1	2	2	2
	Time from first systemic reaction to last systemic reaction [Days]	n	9	8	8	11	11	12	12	71
		Mean (SD)	2.8 (2.7)	2.4 (2.4)	3.3 (3.1)	3.6 (2.3)	3.7 (1.9)	3.4 (1.8)	2.8 (1.6)	3.2 (2.2)
		Min	1	1	1	1	1	1	2	1
		Median	1.0	1.5	1.5	3.0	4.0	3.0	2.0	2.0
		Max	7	8	9	7	7	7	7	9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.1-1: Descriptive statistics of time of solicited systemic reactions - BNT162b1

Safety set

			Younger dose ranging cohorts							
			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	1	2	3	5	8	19
		Mean (SD)	- (-)	- (-)	2.0 (-)	1.5 (-)	1.0 (0.0)	1.2 (0.4)	1.1 (0.4)	1.2 (0.4)
		Min	-	-	2	1	1	1	1	1
		Median	-	-	2.0	1.5	1.0	1.0	1.0	1.0
		Max	-	-	2	2	1	2	2	2
After boost	Time from dose to first systemic reaction [Days]	n	7	7	9	10	11	11	N/A	55
		Mean (SD)	1.3 (0.5)	1.3 (0.8)	1.1 (0.3)	1.1 (0.3)	1.0 (0.0)	1.1 (0.3)	N/A	1.1 (0.4)
		Min	1	1	1	1	1	1	N/A	1
		Median	1.0	1.0	1.0	1.0	1.0	1.0	N/A	1.0
		Max	2	3	2	2	1	2	N/A	3
	Time from dose to first systemic reaction with grade >= 3 [Days]	n	3	1	5	5	6	5	N/A	25
		Mean (SD)	2.3 (1.2)	1.0 (-)	1.4 (0.5)	1.4 (0.5)	1.0 (0.0)	1.0 (0.0)	N/A	1.3 (0.6)
		Min	1	1	1	1	1	1	N/A	1
		Median	3.0	1.0	1.0	1.0	1.0	1.0	N/A	1.0
		Max	3	1	2	2	1	1	N/A	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.1-1: Descriptive statistics of time of solicited systemic reactions - BNT162b1

Safety set

			Younger dose ranging cohorts							
			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Time from first systemic reaction to last systemic reaction [Days]	n	7	7	9	10	11	11	N/A	55
		Mean (SD)	3.6 (2.2)	3.1 (2.3)	3.8 (2.6)	4.2 (1.8)	3.2 (1.6)	3.0 (1.5)	N/A	3.5 (1.9)
		Min	1	1	1	2	2	1	N/A	1
		Median	4.0	3.0	3.0	4.0	2.0	3.0	N/A	3.0
		Max	6	6	8	7	7	6	N/A	8
	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	3	1	5	5	6	5	N/A	25
		Mean (SD)	1.3 (0.6)	1.0 (-)	1.0 (0.0)	1.4 (0.9)	1.3 (0.5)	2.0 (0.7)	N/A	1.4 (0.6)
		Min	1	1	1	1	1	1	N/A	1
		Median	1.0	1.0	1.0	1.0	1.0	2.0	N/A	1.0
		Max	2	1	1	3	2	3	N/A	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.1-1: Descriptive statistics of time of solicited systemic reactions - BNT162b1

Safety set

			Older dose ranging cohorts				
			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Time from dose to first systemic reaction [Days]	n	9	11	11	31	102
		Mean (SD)	1.4 (0.5)	1.5 (0.7)	1.4 (0.5)	1.5 (0.6)	1.3 (0.8)
		Min	1	1	1	1	1
		Median	1.0	1.0	1.0	1.0	1.0
		Max	2	3	2	3	7
	Time from dose to first systemic reaction with grade >= 3 [Days]	n	1	1	2	4	23
		Mean (SD)	2.0 (-)	1.0 (-)	1.5 (-)	1.5 (0.6)	1.4 (0.5)
		Min	2	1	1	1	1
		Median	2.0	1.0	1.5	1.5	1.0
		Max	2	1	2	2	2
	Time from first systemic reaction to last systemic reaction [Days]	n	9	11	11	31	102
		Mean (SD)	2.4 (1.9)	2.5 (1.8)	3.0 (1.9)	2.6 (1.8)	3.0 (2.1)
		Min	1	1	1	1	1
		Median	2.0	2.0	3.0	2.0	2.0
		Max	7	6	7	7	9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.1-1: Descriptive statistics of time of solicited systemic reactions - BNT162b1

Safety set

			Older dose ranging cohorts				
			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	1	1	2	4	23
		Mean (SD)	1.0 (-)	1.0 (-)	1.0 (-)	1.0 (0.0)	1.2 (0.4)
		Min	1	1	1	1	1
		Median	1.0	1.0	1.0	1.0	1.0
		Max	1	1	1	1	2
After boost	Time from dose to first systemic reaction [Days]	n	8	10	12	30	85
		Mean (SD)	1.1 (0.4)	1.4 (0.5)	1.1 (0.3)	1.2 (0.4)	1.2 (0.4)
		Min	1	1	1	1	1
		Median	1.0	1.0	1.0	1.0	1.0
		Max	2	2	2	2	3
	Time from dose to first systemic reaction with grade >= 3 [Days]	n	2	2	4	8	33
		Mean (SD)	1.0 (-)	1.5 (-)	1.3 (0.5)	1.3 (0.5)	1.3 (0.6)
		Min	1	1	1	1	1
		Median	1.0	1.5	1.0	1.0	1.0
		Max	1	2	2	2	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.1-1: Descriptive statistics of time of solicited systemic reactions - BNT162b1

Safety set

			Older dose ranging cohorts				
			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After boost	Time from first systemic reaction to last systemic reaction [Days]	n	8	10	12	30	85
		Mean (SD)	2.8 (1.6)	2.9 (1.7)	3.2 (1.9)	3.0 (1.7)	3.3 (1.9)
		Min	1	1	1	1	1
		Median	2.0	3.0	3.0	3.0	3.0
		Max	6	7	7	7	8
	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	2	2	4	8	33
		Mean (SD)	1.5 (-)	1.0 (-)	1.5 (0.6)	1.4 (0.5)	1.4 (0.6)
		Min	1	1	1	1	1
		Median	1.5	1.0	1.5	1.0	1.0
		Max	2	1	2	2	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Nausea	Time from dose to first systemic reaction [Days]	n	1	0	1	4	1	4	4	15
			Mean (SD)	7.0 (-)	- (-)	2.0 (-)	1.5 (0.6)	1.0 (-)	1.5 (0.6)	1.3 (0.5)	1.8 (1.5)
			Min	7	-	2	1	1	1	1	1
			Median	7.0	-	2.0	1.5	1.0	1.5	1.0	1.0
			Max	7	-	2	2	1	2	2	7
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	1	0	0	0	1	2
			Mean (SD)	- (-)	- (-)	2.0 (-)	- (-)	- (-)	- (-)	1.0 (-)	1.5 (-)
			Min	-	-	2	-	-	-	1	1
			Median	-	-	2.0	-	-	-	1.0	1.5
			Max	-	-	2	-	-	-	1	2
		Time from first systemic reaction to last systemic reaction [Days]	n	1	0	1	4	1	4	4	15
			Mean (SD)	1.0 (-)	- (-)	7.0 (-)	1.8 (1.0)	1.0 (-)	2.3 (0.5)	1.3 (0.5)	2.0 (1.6)
			Min	1	-	7	1	1	2	1	1
			Median	1.0	-	7.0	1.5	1.0	2.0	1.0	2.0
			Max	1	-	7	3	1	3	2	7

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Nausea	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	1	0	0	0	1	2
			Mean (SD)	- (-)	- (-)	1.0 (-)	- (-)	- (-)	- (-)	1.0 (-)	1.0 (-)
			Min	-	-	1	-	-	-	1	1
			Median	-	-	1.0	-	-	-	1.0	1.0
			Max	-	-	1	-	-	-	1	1
	Vomiting	Time from dose to first systemic reaction [Days]	n	0	0	0	0	0	1	1	2
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	1.0 (-)	1.0 (-)	1.0 (-)
			Min	-	-	-	-	-	1	1	1
			Median	-	-	-	-	-	1.0	1.0	1.0
			Max	-	-	-	-	-	1	1	1
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0	1	1
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	1.0 (-)	1.0 (-)
			Min	-	-	-	-	-	-	1	1
			Median	-	-	-	-	-	-	1.0	1.0
			Max	-	-	-	-	-	-	1	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Vomiting	Time from first systemic reaction to last systemic reaction [Days]	n	0	0	0	0	0	1	1	2
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	1.0 (-)	1.0 (-)	1.0 (-)
			Min	-	-	-	-	-	1	1	1
			Median	-	-	-	-	-	1.0	1.0	1.0
			Max	-	-	-	-	-	1	1	1
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0	1	1
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	1.0 (-)	1.0 (-)
			Min	-	-	-	-	-	-	1	1
			Median	-	-	-	-	-	-	1.0	1.0
			Max	-	-	-	-	-	-	1	1
	Diarrhea	Time from dose to first systemic reaction [Days]	n	1	1	2	0	1	1	1	7
			Mean (SD)	1.0 (-)	3.0 (-)	2.5 (-)	- (-)	1.0 (-)	3.0 (-)	4.0 (-)	2.4 (1.1)
			Min	1	3	2	-	1	3	4	1
			Median	1.0	3.0	2.5	-	1.0	3.0	4.0	3.0
			Max	1	3	3	-	1	3	4	4

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Diarrhea	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-	-	-
			Median	-	-	-	-	-	-	-	-
			Max	-	-	-	-	-	-	-	-
		Time from first systemic reaction to last systemic reaction [Days]	n	1	1	2	0	1	1	1	7
			Mean (SD)	7.0 (-)	1.0 (-)	4.0 (-)	- (-)	1.0 (-)	1.0 (-)	2.0 (-)	2.9 (2.5)
			Min	7	1	2	-	1	1	2	1
			Median	7.0	1.0	4.0	-	1.0	1.0	2.0	2.0
			Max	7	1	6	-	1	1	2	7
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-	-	-
			Median	-	-	-	-	-	-	-	-
			Max	-	-	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Headache	Time from dose to first systemic reaction [Days]	n	5	6	5	6	10	10	8	50
			Mean (SD)	3.2 (3.0)	2.5 (2.5)	1.4 (0.5)	1.2 (0.4)	1.1 (0.3)	1.3 (0.5)	1.1 (0.4)	1.6 (1.4)
			Min	1	1	1	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
			Max	7	7	2	2	2	2	2	7
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	1	2	1	2	3	9
			Mean (SD)	- (-)	- (-)	2.0 (-)	1.5 (-)	1.0 (-)	2.0 (-)	1.3 (0.6)	1.6 (0.5)
			Min	-	-	2	1	1	2	1	1
			Median	-	-	2.0	1.5	1.0	2.0	1.0	2.0
			Max	-	-	2	2	1	2	2	2
		Time from first systemic reaction to last systemic reaction [Days]	n	5	6	5	6	10	10	8	50
			Mean (SD)	2.0 (2.2)	1.5 (1.2)	3.6 (3.2)	2.8 (1.9)	2.7 (1.8)	2.8 (1.8)	2.9 (2.1)	2.6 (2.0)
			Min	1	1	1	1	1	1	1	1
			Median	1.0	1.0	2.0	2.5	2.0	2.0	2.0	2.0
			Max	6	4	8	6	7	6	7	8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Headache	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	1	2	1	2	3	9
			Mean (SD)	- (-)	- (-)	2.0 (-)	1.5 (-)	1.0 (-)	1.0 (-)	1.3 (0.6)	1.3 (0.5)
			Min	-	-	2	1	1	1	1	1
			Median	-	-	2.0	1.5	1.0	1.0	1.0	1.0
			Max	-	-	2	2	1	1	2	2
	Fatigue	Time from dose to first systemic reaction [Days]	n	8	6	6	11	8	12	11	62
			Mean (SD)	1.1 (0.4)	1.2 (0.4)	1.5 (0.8)	1.7 (1.8)	1.3 (0.7)	1.4 (0.5)	1.1 (0.3)	1.3 (0.9)
			Min	1	1	1	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
			Max	2	2	3	7	3	2	2	7
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	1	0	1	2	2	6
			Mean (SD)	- (-)	- (-)	2.0 (-)	- (-)	1.0 (-)	2.0 (-)	1.0 (-)	1.5 (0.5)
			Min	-	-	2	-	1	2	1	1
			Median	-	-	2.0	-	1.0	2.0	1.0	1.5
			Max	-	-	2	-	1	2	1	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Fatigue	Time from first systemic reaction to last systemic reaction [Days]	n	8	6	6	11	8	12	11	62
			Mean (SD)	2.3 (2.3)	2.2 (1.2)	3.3 (3.2)	2.6 (1.9)	2.8 (1.5)	2.3 (2.0)	2.1 (1.8)	2.5 (1.9)
			Min	1	1	1	1	1	1	1	1
			Median	1.0	2.0	2.0	2.0	2.5	1.0	2.0	2.0
			Max	6	4	9	6	5	7	7	9
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	1	0	1	2	2	6
			Mean (SD)	- (-)	- (-)	1.0 (-)	- (-)	1.0 (-)	1.0 (-)	1.5 (-)	1.2 (0.4)
			Min	-	-	1	-	1	1	1	1
			Median	-	-	1.0	-	1.0	1.0	1.5	1.0
			Max	-	-	1	-	1	1	2	2
	Myalgia	Time from dose to first systemic reaction [Days]	n	1	0	2	6	6	7	11	33
			Mean (SD)	6.0 (-)	- (-)	2.0 (-)	1.3 (0.5)	1.0 (0.0)	1.9 (1.1)	1.2 (0.4)	1.5 (1.0)
			Min	6	-	2	1	1	1	1	1
			Median	6.0	-	2.0	1.0	1.0	2.0	1.0	1.0
			Max	6	-	2	2	1	4	2	6

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Myalgia	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	1	2	2	0	5
			Mean (SD)	- (-)	- (-)	- (-)	1.0 (-)	1.0 (-)	2.0 (-)	- (-)	1.4 (0.5)
			Min	-	-	-	1	1	2	-	1
			Median	-	-	-	1.0	1.0	2.0	-	1.0
			Max	-	-	-	1	1	2	-	2
		Time from first systemic reaction to last systemic reaction [Days]	n	1	0	2	6	6	7	11	33
			Mean (SD)	1.0 (-)	- (-)	4.5 (-)	2.2 (1.5)	1.7 (0.5)	1.7 (0.5)	2.3 (1.0)	2.1 (1.4)
			Min	1	-	1	1	1	1	1	1
			Median	1.0	-	4.5	1.5	2.0	2.0	2.0	2.0
			Max	1	-	8	4	2	2	4	8
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	1	2	2	0	5
			Mean (SD)	- (-)	- (-)	- (-)	2.0 (-)	1.0 (-)	1.0 (-)	- (-)	1.2 (0.4)
			Min	-	-	-	2	1	1	-	1
			Median	-	-	-	2.0	1.0	1.0	-	1.0
			Max	-	-	-	2	1	1	-	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Arthralgia	Time from dose to first systemic reaction [Days]	n	0	0	1	3	4	5	5	18
			Mean (SD)	- (-)	- (-)	2.0 (-)	2.0 (0.0)	1.0 (0.0)	1.8 (0.4)	1.8 (1.3)	1.7 (0.8)
			Min	-	-	2	2	1	1	1	1
			Median	-	-	2.0	2.0	1.0	2.0	1.0	2.0
			Max	-	-	2	2	1	2	4	4
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	2	1	1	4
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (-)	2.0 (-)	1.0 (-)	1.3 (0.5)
			Min	-	-	-	-	1	2	1	1
			Median	-	-	-	-	1.0	2.0	1.0	1.0
			Max	-	-	-	-	1	2	1	2
		Time from first systemic reaction to last systemic reaction [Days]	n	0	0	1	3	4	5	5	18
			Mean (SD)	- (-)	- (-)	5.0 (-)	2.3 (2.3)	2.0 (0.0)	1.6 (0.5)	1.6 (0.9)	2.0 (1.2)
			Min	-	-	5	1	2	1	1	1
			Median	-	-	5.0	1.0	2.0	2.0	1.0	2.0
			Max	-	-	5	5	2	2	3	5

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Arthralgia	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	2	1	1	4
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (-)	1.0 (-)	1.0 (-)	1.0 (0.0)
			Min	-	-	-	-	1	1	1	1
			Median	-	-	-	-	1.0	1.0	1.0	1.0
			Max	-	-	-	-	1	1	1	1
	Chills	Time from dose to first systemic reaction [Days]	n	2	1	1	4	4	10	10	32
			Mean (SD)	3.5 (-)	2.0 (-)	2.0 (-)	1.3 (0.5)	1.3 (0.5)	1.8 (0.4)	1.0 (0.0)	1.5 (0.9)
			Min	1	2	2	1	1	1	1	1
			Median	3.5	2.0	2.0	1.0	1.0	2.0	1.0	1.0
			Max	6	2	2	2	2	2	1	6
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	1	0	2	3	2	8
			Mean (SD)	- (-)	- (-)	2.0 (-)	- (-)	1.0 (-)	2.0 (0.0)	1.0 (-)	1.5 (0.5)
			Min	-	-	2	-	1	2	1	1
			Median	-	-	2.0	-	1.0	2.0	1.0	1.5
			Max	-	-	2	-	1	2	1	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Chills	Time from first systemic reaction to last systemic reaction [Days]	n	2	1	1	4	4	10	10	32
			Mean (SD)	1.0 (-)	7.0 (-)	7.0 (-)	1.5 (0.6)	1.0 (0.0)	1.2 (0.4)	1.5 (0.5)	1.7 (1.5)
			Min	1	7	7	1	1	1	1	1
			Median	1.0	7.0	7.0	1.5	1.0	1.0	1.5	1.0
			Max	1	7	7	2	1	2	2	7
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	1	0	2	3	2	8
			Mean (SD)	- (-)	- (-)	1.0 (-)	- (-)	1.0 (-)	1.0 (0.0)	1.0 (-)	1.0 (0.0)
			Min	-	-	1	-	1	1	1	1
			Median	-	-	1.0	-	1.0	1.0	1.0	1.0
			Max	-	-	1	-	1	1	1	1
	Loss of Appetite	Time from dose to first systemic reaction [Days]	n	0	0	1	3	3	7	6	20
			Mean (SD)	- (-)	- (-)	2.0 (-)	1.3 (0.6)	1.7 (0.6)	1.9 (0.4)	1.2 (0.4)	1.6 (0.5)
			Min	-	-	2	1	1	1	1	1
			Median	-	-	2.0	1.0	2.0	2.0	1.0	2.0
			Max	-	-	2	2	2	2	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Loss of Appetite	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	1	1	2
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	2.0 (-)	1.0 (-)	1.5 (-)
			Min	-	-	-	-	-	2	1	1
			Median	-	-	-	-	-	2.0	1.0	1.5
			Max	-	-	-	-	-	2	1	2
		Time from first systemic reaction to last systemic reaction [Days]	n	0	0	1	3	3	7	6	20
			Mean (SD)	- (-)	- (-)	7.0 (-)	2.0 (1.0)	1.0 (0.0)	2.4 (1.4)	1.5 (0.5)	2.1 (1.6)
			Min	-	-	7	1	1	1	1	1
			Median	-	-	7.0	2.0	1.0	2.0	1.5	2.0
			Max	-	-	7	3	1	5	2	7
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	1	1	2
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	2.0 (-)	2.0 (-)	2.0 (-)
			Min	-	-	-	-	-	2	2	2
			Median	-	-	-	-	-	2.0	2.0	2.0
			Max	-	-	-	-	-	2	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Malaise	Time from dose to first systemic reaction [Days]	n	2	0	1	6	8	10	9	36
			Mean (SD)	6.0 (-)	- (-)	2.0 (-)	1.0 (0.0)	1.5 (0.8)	1.4 (0.5)	1.3 (0.7)	1.6 (1.2)
			Min	6	-	2	1	1	1	1	1
			Median	6.0	-	2.0	1.0	1.0	1.0	1.0	1.0
			Max	6	-	2	1	3	2	3	6
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	2	2	3	7
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (-)	2.0 (-)	1.0 (0.0)	1.3 (0.5)
			Min	-	-	-	-	1	2	1	1
			Median	-	-	-	-	1.0	2.0	1.0	1.0
			Max	-	-	-	-	1	2	1	2
		Time from first systemic reaction to last systemic reaction [Days]	n	2	0	1	6	8	10	9	36
			Mean (SD)	1.0 (-)	- (-)	8.0 (-)	2.0 (0.9)	2.0 (1.3)	2.5 (1.8)	1.7 (0.7)	2.2 (1.6)
			Min	1	-	8	1	1	1	1	1
			Median	1.0	-	8.0	2.0	2.0	2.0	2.0	2.0
			Max	1	-	8	3	5	7	3	8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Malaise	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	2	2	3	7
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (-)	1.0 (-)	1.3 (0.6)	1.1 (0.4)
			Min	-	-	-	-	1	1	1	1
			Median	-	-	-	-	1.0	1.0	1.0	1.0
			Max	-	-	-	-	1	1	2	2
	Fever	Time from dose to first systemic reaction [Days]	n	0	0	0	0	1	4	4	9
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (-)	2.0 (0.0)	1.0 (0.0)	1.4 (0.5)
			Min	-	-	-	-	1	2	1	1
			Median	-	-	-	-	1.0	2.0	1.0	1.0
			Max	-	-	-	-	1	2	1	2
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0	1	1
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	1.0 (-)	1.0 (-)
			Min	-	-	-	-	-	-	1	1
			Median	-	-	-	-	-	-	1.0	1.0
			Max	-	-	-	-	-	-	1	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Fever	Time from first systemic reaction to last systemic reaction [Days]	n	0	0	0	0	1	4	4	9
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (-)	1.0 (0.0)	1.3 (0.5)	1.1 (0.3)
			Min	-	-	-	-	1	1	1	1
			Median	-	-	-	-	1.0	1.0	1.0	1.0
			Max	-	-	-	-	1	1	2	2
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0	1	1
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	1.0 (-)	1.0 (-)
			Min	-	-	-	-	-	-	1	1
			Median	-	-	-	-	-	-	1.0	1.0
			Max	-	-	-	-	-	-	1	1
After boost	Nausea	Time from dose to first systemic reaction [Days]	n	2	1	3	3	3	4	N/A	16
			Mean (SD)	1.5 (-)	2.0 (-)	1.3 (0.6)	1.0 (0.0)	1.3 (0.6)	1.0 (0.0)	N/A	1.3 (0.4)
			Min	1	2	1	1	1	1	N/A	1
			Median	1.5	2.0	1.0	1.0	1.0	1.0	N/A	1.0
			Max	2	2	2	1	2	1	N/A	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Nausea	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	1	0	0	1	N/A	2
			Mean (SD)	- (-)	- (-)	1.0 (-)	- (-)	- (-)	2.0 (-)	N/A	1.5 (-)
			Min	-	-	1	-	-	2	N/A	1
			Median	-	-	1.0	-	-	2.0	N/A	1.5
			Max	-	-	1	-	-	2	N/A	2
		Time from first systemic reaction to last systemic reaction [Days]	n	2	1	3	3	3	4	N/A	16
			Mean (SD)	4.5 (-)	1.0 (-)	1.3 (0.6)	2.0 (1.7)	1.7 (1.2)	2.0 (1.4)	N/A	2.1 (1.4)
			Min	4	1	1	1	1	1	N/A	1
			Median	4.5	1.0	1.0	1.0	1.0	1.5	N/A	1.0
			Max	5	1	2	4	3	4	N/A	5
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	1	0	0	1	N/A	2
			Mean (SD)	- (-)	- (-)	1.0 (-)	- (-)	- (-)	2.0 (-)	N/A	1.5 (-)
			Min	-	-	1	-	-	2	N/A	1
			Median	-	-	1.0	-	-	2.0	N/A	1.5
			Max	-	-	1	-	-	2	N/A	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Vomiting	Time from dose to first systemic reaction [Days]	n	0	0	0	1	0	1	N/A	2
			Mean (SD)	- (-)	- (-)	- (-)	1.0 (-)	- (-)	1.0 (-)	N/A	1.0 (-)
			Min	-	-	-	1	-	1	N/A	1
			Median	-	-	-	1.0	-	1.0	N/A	1.0
			Max	-	-	-	1	-	1	N/A	1
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0	N/A	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	N/A	- (-)
			Min	-	-	-	-	-	-	N/A	-
			Median	-	-	-	-	-	-	N/A	-
			Max	-	-	-	-	-	-	N/A	-
		Time from first systemic reaction to last systemic reaction [Days]	n	0	0	0	1	0	1	N/A	2
			Mean (SD)	- (-)	- (-)	- (-)	3.0 (-)	- (-)	1.0 (-)	N/A	2.0 (-)
			Min	-	-	-	3	-	1	N/A	1
			Median	-	-	-	3.0	-	1.0	N/A	2.0
			Max	-	-	-	3	-	1	N/A	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Vomiting	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0	N/A	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	N/A	- (-)
			Min	-	-	-	-	-	-	N/A	-
			Median	-	-	-	-	-	-	N/A	-
			Max	-	-	-	-	-	-	N/A	-
	Diarrhea	Time from dose to first systemic reaction [Days]	n	0	0	0	1	0	1	N/A	2
			Mean (SD)	- (-)	- (-)	- (-)	1.0 (-)	- (-)	2.0 (-)	N/A	1.5 (-)
			Min	-	-	-	1	-	2	N/A	1
			Median	-	-	-	1.0	-	2.0	N/A	1.5
			Max	-	-	-	1	-	2	N/A	2
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	1	0	0	N/A	1
			Mean (SD)	- (-)	- (-)	- (-)	1.0 (-)	- (-)	- (-)	N/A	1.0 (-)
			Min	-	-	-	1	-	-	N/A	1
			Median	-	-	-	1.0	-	-	N/A	1.0
			Max	-	-	-	1	-	-	N/A	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Diarrhea	Time from first systemic reaction to last systemic reaction [Days]	n	0	0	0	1	0	1	N/A	2
			Mean (SD)	- (-)	- (-)	- (-)	4.0 (-)	- (-)	1.0 (-)	N/A	2.5 (-)
			Min	-	-	-	4	-	1	N/A	1
			Median	-	-	-	4.0	-	1.0	N/A	2.5
			Max	-	-	-	4	-	1	N/A	4
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	1	0	0	N/A	1
			Mean (SD)	- (-)	- (-)	- (-)	3.0 (-)	- (-)	- (-)	N/A	3.0 (-)
			Min	-	-	-	3	-	-	N/A	3
			Median	-	-	-	3.0	-	-	N/A	3.0
			Max	-	-	-	3	-	-	N/A	3
	Headache	Time from dose to first systemic reaction [Days]	n	7	6	8	9	10	9	N/A	49
			Mean (SD)	1.7 (1.5)	1.5 (0.8)	1.1 (0.4)	1.1 (0.3)	1.0 (0.0)	1.1 (0.3)	N/A	1.2 (0.7)
			Min	1	1	1	1	1	1	N/A	1
			Median	1.0	1.0	1.0	1.0	1.0	1.0	N/A	1.0
			Max	5	3	2	2	1	2	N/A	5

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Headache	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	1	3	5	4	N/A	13
			Mean (SD)	- (-)	- (-)	2.0 (-)	1.7 (0.6)	1.0 (0.0)	1.0 (0.0)	N/A	1.2 (0.4)
			Min	-	-	2	1	1	1	N/A	1
			Median	-	-	2.0	2.0	1.0	1.0	N/A	1.0
			Max	-	-	2	2	1	1	N/A	2
		Time from first systemic reaction to last systemic reaction [Days]	n	7	6	8	9	10	9	N/A	49
			Mean (SD)	2.3 (1.8)	2.7 (2.1)	3.0 (2.4)	3.4 (1.4)	3.0 (1.6)	2.4 (0.9)	N/A	2.8 (1.7)
			Min	1	1	1	2	2	1	N/A	1
			Median	2.0	2.0	2.0	3.0	2.0	2.0	N/A	2.0
			Max	6	6	8	6	7	4	N/A	8
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	1	3	5	4	N/A	13
			Mean (SD)	- (-)	- (-)	1.0 (-)	1.0 (0.0)	1.4 (0.5)	2.3 (0.5)	N/A	1.5 (0.7)
			Min	-	-	1	1	1	2	N/A	1
			Median	-	-	1.0	1.0	1.0	2.0	N/A	1.0
			Max	-	-	1	1	2	3	N/A	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Fatigue	Time from dose to first systemic reaction [Days]	n	5	6	6	6	10	9	N/A	42
			Mean (SD)	1.4 (0.5)	1.3 (0.8)	1.0 (0.0)	1.3 (0.8)	1.2 (0.4)	1.0 (0.0)	N/A	1.2 (0.5)
			Min	1	1	1	1	1	1	N/A	1
			Median	1.0	1.0	1.0	1.0	1.0	1.0	N/A	1.0
			Max	2	3	1	3	2	1	N/A	3
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	1	1	0	1	3	3	N/A	9
			Mean (SD)	3.0 (-)	1.0 (-)	- (-)	2.0 (-)	1.0 (0.0)	1.0 (0.0)	N/A	1.3 (0.7)
			Min	3	1	-	2	1	1	N/A	1
			Median	3.0	1.0	-	2.0	1.0	1.0	N/A	1.0
			Max	3	1	-	2	1	1	N/A	3
		Time from first systemic reaction to last systemic reaction [Days]	n	5	6	6	6	10	9	N/A	42
			Mean (SD)	3.2 (2.3)	2.8 (1.9)	3.3 (2.3)	3.3 (2.3)	2.1 (1.4)	2.9 (1.5)	N/A	2.9 (1.8)
			Min	1	1	2	1	1	1	N/A	1
			Median	3.0	2.5	2.5	3.5	2.0	2.0	N/A	2.0
			Max	6	6	8	6	5	6	N/A	8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Fatigue	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	1	1	0	1	3	3	N/A	9
			Mean (SD)	1.0 (-)	1.0 (-)	- (-)	1.0 (-)	1.0 (0.0)	2.0 (0.0)	N/A	1.3 (0.5)
			Min	1	1	-	1	1	2	N/A	1
			Median	1.0	1.0	-	1.0	1.0	2.0	N/A	1.0
			Max	1	1	-	1	1	2	N/A	2
	Myalgia	Time from dose to first systemic reaction [Days]	n	5	2	6	5	9	6	N/A	33
			Mean (SD)	1.4 (0.5)	1.5 (-)	1.5 (0.5)	1.2 (0.4)	1.1 (0.3)	1.0 (0.0)	N/A	1.2 (0.4)
			Min	1	1	1	1	1	1	N/A	1
			Median	1.0	1.5	1.5	1.0	1.0	1.0	N/A	1.0
			Max	2	2	2	2	2	1	N/A	2
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	1	1	3	0	N/A	5
			Mean (SD)	- (-)	- (-)	2.0 (-)	2.0 (-)	1.0 (0.0)	- (-)	N/A	1.4 (0.5)
			Min	-	-	2	2	1	-	N/A	1
			Median	-	-	2.0	2.0	1.0	-	N/A	1.0
			Max	-	-	2	2	1	-	N/A	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Myalgia	Time from first systemic reaction to last systemic reaction [Days]	n	5	2	6	5	9	6	N/A	33
			Mean (SD)	2.0 (1.7)	3.0 (-)	2.3 (1.4)	3.6 (2.2)	2.3 (1.1)	3.0 (1.3)	N/A	2.6 (1.5)
			Min	1	1	1	1	1	1	N/A	1
			Median	1.0	3.0	2.0	3.0	2.0	3.5	N/A	2.0
			Max	5	5	5	7	4	4	N/A	7
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	1	1	3	0	N/A	5
			Mean (SD)	- (-)	- (-)	1.0 (-)	1.0 (-)	1.0 (0.0)	- (-)	N/A	1.0 (0.0)
			Min	-	-	1	1	1	-	N/A	1
			Median	-	-	1.0	1.0	1.0	-	N/A	1.0
			Max	-	-	1	1	1	-	N/A	1
	Arthralgia	Time from dose to first systemic reaction [Days]	n	2	1	3	1	8	6	N/A	21
			Mean (SD)	2.0 (-)	2.0 (-)	1.7 (0.6)	1.0 (-)	1.1 (0.4)	1.0 (0.0)	N/A	1.3 (0.5)
			Min	2	2	1	1	1	1	N/A	1
			Median	2.0	2.0	2.0	1.0	1.0	1.0	N/A	1.0
			Max	2	2	2	1	2	1	N/A	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Arthralgia	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	3	0	N/A	3
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (0.0)	- (-)	N/A	1.0 (0.0)
			Min	-	-	-	-	1	-	N/A	1
			Median	-	-	-	-	1.0	-	N/A	1.0
			Max	-	-	-	-	1	-	N/A	1
		Time from first systemic reaction to last systemic reaction [Days]	n	2	1	3	1	8	6	N/A	21
			Mean (SD)	3.0 (-)	1.0 (-)	1.7 (1.2)	5.0 (-)	2.0 (0.8)	2.7 (1.2)	N/A	2.3 (1.3)
			Min	1	1	1	5	1	1	N/A	1
			Median	3.0	1.0	1.0	5.0	2.0	2.5	N/A	2.0
			Max	5	1	3	5	3	4	N/A	5
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	3	0	N/A	3
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (0.0)	- (-)	N/A	1.0 (0.0)
			Min	-	-	-	-	1	-	N/A	1
			Median	-	-	-	-	1.0	-	N/A	1.0
			Max	-	-	-	-	1	-	N/A	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Chills	Time from dose to first systemic reaction [Days]	n	4	1	5	5	9	9	N/A	33
			Mean (SD)	1.5 (0.6)	3.0 (-)	1.2 (0.4)	1.2 (0.4)	1.2 (0.4)	1.1 (0.3)	N/A	1.3 (0.5)
			Min	1	3	1	1	1	1	N/A	1
			Median	1.5	3.0	1.0	1.0	1.0	1.0	N/A	1.0
			Max	2	3	2	2	2	2	N/A	3
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	2	3	4	3	N/A	12
			Mean (SD)	- (-)	- (-)	1.0 (-)	1.3 (0.6)	1.0 (0.0)	1.0 (0.0)	N/A	1.1 (0.3)
			Min	-	-	1	1	1	1	N/A	1
			Median	-	-	1.0	1.0	1.0	1.0	N/A	1.0
			Max	-	-	1	2	1	1	N/A	2
		Time from first systemic reaction to last systemic reaction [Days]	n	4	1	5	5	9	9	N/A	33
			Mean (SD)	1.0 (0.0)	2.0 (-)	1.8 (0.4)	2.2 (1.8)	1.7 (0.7)	1.8 (0.7)	N/A	1.7 (0.9)
			Min	1	2	1	1	1	1	N/A	1
			Median	1.0	2.0	2.0	1.0	2.0	2.0	N/A	2.0
			Max	1	2	2	5	3	3	N/A	5

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Chills	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	2	3	4	3	N/A	12
			Mean (SD)	- (-)	- (-)	1.0 (-)	1.3 (0.6)	1.0 (0.0)	1.7 (0.6)	N/A	1.3 (0.5)
			Min	-	-	1	1	1	1	N/A	1
			Median	-	-	1.0	1.0	1.0	2.0	N/A	1.0
			Max	-	-	1	2	1	2	N/A	2
	Loss of Appetite	Time from dose to first systemic reaction [Days]	n	2	1	5	4	5	8	N/A	25
			Mean (SD)	1.0 (-)	2.0 (-)	1.8 (0.4)	1.3 (0.5)	1.8 (0.4)	1.3 (0.5)	N/A	1.5 (0.5)
			Min	1	2	1	1	1	1	N/A	1
			Median	1.0	2.0	2.0	1.0	2.0	1.0	N/A	1.0
			Max	1	2	2	2	2	2	N/A	2
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	1	0	1	1	1	4	N/A	8
			Mean (SD)	3.0 (-)	- (-)	1.0 (-)	1.0 (-)	1.0 (-)	1.3 (0.5)	N/A	1.4 (0.7)
			Min	3	-	1	1	1	1	N/A	1
			Median	3.0	-	1.0	1.0	1.0	1.0	N/A	1.0
			Max	3	-	1	1	1	2	N/A	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Loss of Appetite	Time from first systemic reaction to last systemic reaction [Days]	n	2	1	5	4	5	8	N/A	25
			Mean (SD)	5.5 (-)	1.0 (-)	1.2 (0.4)	3.0 (1.4)	1.0 (0.0)	2.5 (1.6)	N/A	2.2 (1.6)
			Min	5	1	1	2	1	1	N/A	1
			Median	5.5	1.0	1.0	2.5	1.0	2.0	N/A	1.0
			Max	6	1	2	5	1	5	N/A	6
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	1	0	1	1	1	4	N/A	8
			Mean (SD)	2.0 (-)	- (-)	1.0 (-)	2.0 (-)	1.0 (-)	1.8 (0.5)	N/A	1.6 (0.5)
			Min	2	-	1	2	1	1	N/A	1
			Median	2.0	-	1.0	2.0	1.0	2.0	N/A	2.0
			Max	2	-	1	2	1	2	N/A	2
	Malaise	Time from dose to first systemic reaction [Days]	n	2	2	6	5	10	10	N/A	35
			Mean (SD)	1.0 (-)	1.5 (-)	1.7 (0.5)	1.4 (0.5)	1.2 (0.4)	1.1 (0.3)	N/A	1.3 (0.5)
			Min	1	1	1	1	1	1	N/A	1
			Median	1.0	1.5	2.0	1.0	1.0	1.0	N/A	1.0
			Max	1	2	2	2	2	2	N/A	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Malaise	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	1	1	5	4	N/A	11
			Mean (SD)	- (-)	- (-)	1.0 (-)	1.0 (-)	1.0 (0.0)	1.0 (0.0)	N/A	1.0 (0.0)
			Min	-	-	1	1	1	1	N/A	1
			Median	-	-	1.0	1.0	1.0	1.0	N/A	1.0
			Max	-	-	1	1	1	1	N/A	1
		Time from first systemic reaction to last systemic reaction [Days]	n	2	2	6	5	10	10	N/A	35
			Mean (SD)	5.5 (-)	4.0 (-)	2.3 (2.0)	2.8 (1.6)	2.7 (1.8)	2.3 (0.9)	N/A	2.8 (1.7)
			Min	5	2	1	1	1	1	N/A	1
			Median	5.5	4.0	1.5	2.0	2.0	2.0	N/A	2.0
			Max	6	6	6	5	7	4	N/A	7
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	1	1	5	4	N/A	11
			Mean (SD)	- (-)	- (-)	1.0 (-)	3.0 (-)	1.2 (0.4)	2.0 (0.0)	N/A	1.6 (0.7)
			Min	-	-	1	3	1	2	N/A	1
			Median	-	-	1.0	3.0	1.0	2.0	N/A	2.0
			Max	-	-	1	3	2	2	N/A	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Fever	Time from dose to first systemic reaction [Days]	n	1	1	4	4	5	6	N/A	21
			Mean (SD)	1.0 (-)	2.0 (-)	1.3 (0.5)	1.3 (0.5)	1.4 (0.5)	1.3 (0.5)	N/A	1.3 (0.5)
			Min	1	2	1	1	1	1	N/A	1
			Median	1.0	2.0	1.0	1.0	1.0	1.0	N/A	1.0
			Max	1	2	2	2	2	2	N/A	2
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	1	0	1	2	1	2	N/A	7
			Mean (SD)	1.0 (-)	- (-)	1.0 (-)	1.5 (-)	1.0 (-)	1.0 (-)	N/A	1.1 (0.4)
			Min	1	-	1	1	1	1	N/A	1
			Median	1.0	-	1.0	1.5	1.0	1.0	N/A	1.0
			Max	1	-	1	2	1	1	N/A	2
		Time from first systemic reaction to last systemic reaction [Days]	n	1	1	4	4	5	6	N/A	21
			Mean (SD)	1.0 (-)	1.0 (-)	1.3 (0.5)	1.5 (0.6)	1.0 (0.0)	1.7 (0.5)	N/A	1.3 (0.5)
			Min	1	1	1	1	1	1	N/A	1
			Median	1.0	1.0	1.0	1.5	1.0	2.0	N/A	1.0
			Max	1	1	2	2	1	2	N/A	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Younger dose ranging cohorts							
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Fever	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	1	0	1	2	1	2	N/A	7
			Mean (SD)	1.0 (-)	- (-)	1.0 (-)	1.0 (-)	1.0 (-)	1.0 (-)	N/A	1.0 (0.0)
			Min	1	-	1	1	1	1	N/A	1
			Median	1.0	-	1.0	1.0	1.0	1.0	N/A	1.0
			Max	1	-	1	1	1	1	N/A	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Nausea	Time from dose to first systemic reaction [Days]	n	1	1	2	4	19
			Mean (SD)	2.0 (-)	4.0 (-)	1.5 (-)	2.3 (1.3)	1.9 (1.4)
			Min	2	4	1	1	1
			Median	2.0	4.0	1.5	2.0	2.0
			Max	2	4	2	4	7
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	2
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.5 (-)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.5
			Max	-	-	-	-	2
		Time from first systemic reaction to last systemic reaction [Days]	n	1	1	2	4	19
			Mean (SD)	1.0 (-)	1.0 (-)	1.0 (-)	1.0 (0.0)	1.8 (1.4)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	1	1	1	1	7

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Nausea	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	2
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (-)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	1
	Vomiting	Time from dose to first systemic reaction [Days]	n	1	0	0	1	3
			Mean (SD)	2.0 (-)	- (-)	- (-)	2.0 (-)	1.3 (0.6)
			Min	2	-	-	2	1
			Median	2.0	-	-	2.0	1.0
			Max	2	-	-	2	2
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	1
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (-)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Vomiting	Time from first systemic reaction to last systemic reaction [Days]	n	1	0	0	1	3
			Mean (SD)	1.0 (-)	- (-)	- (-)	1.0 (-)	1.0 (0.0)
			Min	1	-	-	1	1
			Median	1.0	-	-	1.0	1.0
			Max	1	-	-	1	1
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	1
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (-)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	1
	Diarrhea	Time from dose to first systemic reaction [Days]	n	0	2	1	3	10
			Mean (SD)	- (-)	1.0 (-)	1.0 (-)	1.0 (0.0)	2.0 (1.2)
			Min	-	1	1	1	1
			Median	-	1.0	1.0	1.0	1.5
			Max	-	1	1	1	4

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Diarrhea	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from first systemic reaction to last systemic reaction [Days]	n	0	2	1	3	10
			Mean (SD)	- (-)	1.0 (-)	1.0 (-)	1.0 (0.0)	2.3 (2.3)
			Min	-	1	1	1	1
			Median	-	1.0	1.0	1.0	1.0
			Max	-	1	1	1	7
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Headache	Time from dose to first systemic reaction [Days]	n	8	6	4	18	68
			Mean (SD)	1.8 (1.0)	2.2 (0.8)	1.3 (0.5)	1.8 (0.9)	1.6 (1.3)
			Min	1	1	1	1	1
			Median	1.5	2.0	1.0	2.0	1.0
			Max	4	3	2	4	7
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	1	0	2	3	12
			Mean (SD)	2.0 (-)	- (-)	1.5 (-)	1.7 (0.6)	1.6 (0.5)
			Min	2	-	1	1	1
			Median	2.0	-	1.5	2.0	2.0
			Max	2	-	2	2	2
		Time from first systemic reaction to last systemic reaction [Days]	n	8	6	4	18	68
			Mean (SD)	2.0 (0.9)	1.7 (1.0)	1.8 (0.5)	1.8 (0.9)	2.4 (1.8)
			Min	1	1	1	1	1
			Median	2.0	1.0	2.0	2.0	2.0
			Max	4	3	2	4	8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Headache	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	1	0	2	3	12
			Mean (SD)	1.0 (-)	- (-)	1.0 (-)	1.0 (0.0)	1.3 (0.5)
			Min	1	-	1	1	1
			Median	1.0	-	1.0	1.0	1.0
			Max	1	-	1	1	2
	Fatigue	Time from dose to first systemic reaction [Days]	n	6	7	9	22	84
			Mean (SD)	1.5 (0.5)	1.6 (0.5)	1.4 (0.5)	1.5 (0.5)	1.4 (0.8)
			Min	1	1	1	1	1
			Median	1.5	2.0	1.0	1.5	1.0
			Max	2	2	2	2	7
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	1	1	1	3	9
			Mean (SD)	2.0 (-)	1.0 (-)	1.0 (-)	1.3 (0.6)	1.4 (0.5)
			Min	2	1	1	1	1
			Median	2.0	1.0	1.0	1.0	1.0
			Max	2	1	1	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Fatigue	Time from first systemic reaction to last systemic reaction [Days]	n	6	7	9	22	84
			Mean (SD)	2.0 (1.7)	2.0 (1.4)	2.4 (1.9)	2.2 (1.7)	2.4 (1.9)
			Min	1	1	1	1	1
			Median	1.0	2.0	2.0	1.5	2.0
			Max	5	5	7	7	9
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	1	1	1	3	9
			Mean (SD)	1.0 (-)	1.0 (-)	1.0 (-)	1.0 (0.0)	1.1 (0.3)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	1	1	1	1	2
	Myalgia	Time from dose to first systemic reaction [Days]	n	2	5	7	14	47
			Mean (SD)	1.5 (-)	1.6 (0.5)	2.1 (1.5)	1.9 (1.1)	1.6 (1.1)
			Min	1	1	1	1	1
			Median	1.5	2.0	2.0	2.0	1.0
			Max	2	2	5	5	6

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Myalgia	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	5
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.4 (0.5)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	2
		Time from first systemic reaction to last systemic reaction [Days]	n	2	5	7	14	47
			Mean (SD)	1.5 (-)	2.6 (1.5)	2.0 (0.8)	2.1 (1.1)	2.1 (1.3)
			Min	1	1	1	1	1
			Median	1.5	2.0	2.0	2.0	2.0
			Max	2	5	3	5	8
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	5
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.2 (0.4)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Arthralgia	Time from dose to first systemic reaction [Days]	n	1	3	4	8	26
			Mean (SD)	2.0 (-)	2.0 (0.0)	1.8 (0.5)	1.9 (0.4)	1.7 (0.7)
			Min	2	2	1	1	1
			Median	2.0	2.0	2.0	2.0	2.0
			Max	2	2	2	2	4
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	4
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.3 (0.5)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	2
		Time from first systemic reaction to last systemic reaction [Days]	n	1	3	4	8	26
			Mean (SD)	1.0 (-)	2.3 (1.5)	2.8 (2.4)	2.4 (1.8)	2.1 (1.4)
			Min	1	1	1	1	1
			Median	1.0	2.0	2.0	1.5	2.0
			Max	1	4	6	6	6

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Arthralgia	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	4
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (0.0)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	1
	Chills	Time from dose to first systemic reaction [Days]	n	1	3	3	7	39
			Mean (SD)	2.0 (-)	3.0 (1.7)	2.7 (2.1)	2.7 (1.6)	1.7 (1.2)
			Min	2	2	1	1	1
			Median	2.0	2.0	2.0	2.0	1.0
			Max	2	5	5	5	6
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	8
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.5 (0.5)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.5
			Max	-	-	-	-	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Chills	Time from first systemic reaction to last systemic reaction [Days]	n	1	3	3	7	39
			Mean (SD)	1.0 (-)	1.0 (0.0)	1.7 (0.6)	1.3 (0.5)	1.6 (1.4)
			Min	1	1	1	1	1
			Median	1.0	1.0	2.0	1.0	1.0
			Max	1	1	2	2	7
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	8
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (0.0)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	1
	Loss of Appetite	Time from dose to first systemic reaction [Days]	n	1	0	2	3	23
			Mean (SD)	2.0 (-)	- (-)	1.5 (-)	1.7 (0.6)	1.6 (0.5)
			Min	2	-	1	1	1
			Median	2.0	-	1.5	2.0	2.0
			Max	2	-	2	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Loss of Appetite	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	2
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.5 (-)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.5
			Max	-	-	-	-	2
		Time from first systemic reaction to last systemic reaction [Days]	n	1	0	2	3	23
			Mean (SD)	3.0 (-)	- (-)	3.5 (-)	3.3 (2.5)	2.3 (1.7)
			Min	3	-	1	1	1
			Median	3.0	-	3.5	3.0	2.0
			Max	3	-	6	6	7
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	2
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	2.0 (-)
			Min	-	-	-	-	2
			Median	-	-	-	-	2.0
			Max	-	-	-	-	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Malaise	Time from dose to first systemic reaction [Days]	n	3	1	4	8	44
			Mean (SD)	1.7 (0.6)	4.0 (-)	1.8 (0.5)	2.0 (0.9)	1.7 (1.2)
			Min	1	4	1	1	1
			Median	2.0	4.0	2.0	2.0	1.0
			Max	2	4	2	4	6
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	1	0	1	2	9
			Mean (SD)	2.0 (-)	- (-)	1.0 (-)	1.5 (-)	1.3 (0.5)
			Min	2	-	1	1	1
			Median	2.0	-	1.0	1.5	1.0
			Max	2	-	1	2	2
		Time from first systemic reaction to last systemic reaction [Days]	n	3	1	4	8	44
			Mean (SD)	1.0 (0.0)	1.0 (-)	1.5 (1.0)	1.3 (0.7)	2.0 (1.5)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	2.0
			Max	1	1	3	3	8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Malaise	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	1	0	1	2	9
			Mean (SD)	1.0 (-)	- (-)	1.0 (-)	1.0 (-)	1.1 (0.3)
			Min	1	-	1	1	1
			Median	1.0	-	1.0	1.0	1.0
			Max	1	-	1	1	2
	Fever	Time from dose to first systemic reaction [Days]	n	0	0	0	0	9
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.4 (0.5)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	2
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	1
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (-)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After prime	Fever	Time from first systemic reaction to last systemic reaction [Days]	n	0	0	0	0	9
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.1 (0.3)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	2
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	1
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (-)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	1
After boost	Nausea	Time from dose to first systemic reaction [Days]	n	1	2	4	7	23
			Mean (SD)	1.0 (-)	1.5 (-)	1.3 (0.5)	1.3 (0.5)	1.3 (0.4)
			Min	1	1	1	1	1
			Median	1.0	1.5	1.0	1.0	1.0
			Max	1	2	2	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After boost	Nausea	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	2
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.5 (-)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.5
			Max	-	-	-	-	2
		Time from first systemic reaction to last systemic reaction [Days]	n	1	2	4	7	23
			Mean (SD)	1.0 (-)	1.0 (-)	1.5 (0.6)	1.3 (0.5)	1.8 (1.3)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.5	1.0	1.0
			Max	1	1	2	2	5
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	2
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.5 (-)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.5
			Max	-	-	-	-	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After boost	Vomiting	Time from dose to first systemic reaction [Days]	n	1	0	1	2	4
			Mean (SD)	1.0 (-)	- (-)	1.0 (-)	1.0 (-)	1.0 (0.0)
			Min	1	-	1	1	1
			Median	1.0	-	1.0	1.0	1.0
			Max	1	-	1	1	1
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from first systemic reaction to last systemic reaction [Days]	n	1	0	1	2	4
			Mean (SD)	1.0 (-)	- (-)	1.0 (-)	1.0 (-)	1.5 (1.0)
			Min	1	-	1	1	1
			Median	1.0	-	1.0	1.0	1.0
			Max	1	-	1	1	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After boost	Vomiting	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
	Diarrhea	Time from dose to first systemic reaction [Days]	n	0	0	0	0	2
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.5 (-)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.5
			Max	-	-	-	-	2
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	1
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (-)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After boost	Diarrhea	Time from first systemic reaction to last systemic reaction [Days]	n	0	0	0	0	2
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	2.5 (-)
			Min	-	-	-	-	1
			Median	-	-	-	-	2.5
			Max	-	-	-	-	4
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	1
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	3.0 (-)
			Min	-	-	-	-	3
			Median	-	-	-	-	3.0
			Max	-	-	-	-	3
	Headache	Time from dose to first systemic reaction [Days]	n	8	9	10	27	76
			Mean (SD)	1.3 (0.5)	1.7 (0.5)	1.1 (0.3)	1.3 (0.5)	1.3 (0.6)
			Min	1	1	1	1	1
			Median	1.0	2.0	1.0	1.0	1.0
			Max	2	2	2	2	5

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After boost	Headache	Time from dose to first systemic reaction with grade >= 3 [Days]	n	2	0	0	2	15
			Mean (SD)	1.0 (-)	- (-)	- (-)	1.0 (-)	1.2 (0.4)
			Min	1	-	-	1	1
			Median	1.0	-	-	1.0	1.0
			Max	1	-	-	1	2
		Time from first systemic reaction to last systemic reaction [Days]	n	8	9	10	27	76
			Mean (SD)	2.4 (1.6)	1.4 (0.7)	1.8 (0.6)	1.9 (1.1)	2.5 (1.6)
			Min	1	1	1	1	1
			Median	2.0	1.0	2.0	2.0	2.0
			Max	6	3	3	6	8
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	2	0	0	2	15
			Mean (SD)	1.0 (-)	- (-)	- (-)	1.0 (-)	1.5 (0.6)
			Min	1	-	-	1	1
			Median	1.0	-	-	1.0	1.0
			Max	1	-	-	1	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After boost	Fatigue	Time from dose to first systemic reaction [Days]	n	4	7	12	23	65
			Mean (SD)	1.3 (0.5)	1.7 (0.5)	1.2 (0.4)	1.3 (0.5)	1.2 (0.5)
			Min	1	1	1	1	1
			Median	1.0	2.0	1.0	1.0	1.0
			Max	2	2	2	2	3
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	3	3	12
			Mean (SD)	- (-)	- (-)	1.3 (0.6)	1.3 (0.6)	1.3 (0.7)
			Min	-	-	1	1	1
			Median	-	-	1.0	1.0	1.0
			Max	-	-	2	2	3
		Time from first systemic reaction to last systemic reaction [Days]	n	4	7	12	23	65
			Mean (SD)	1.5 (0.6)	1.1 (0.4)	2.3 (1.7)	1.8 (1.3)	2.5 (1.7)
			Min	1	1	1	1	1
			Median	1.5	1.0	2.0	1.0	2.0
			Max	2	2	7	7	8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After boost	Fatigue	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	3	3	12
			Mean (SD)	- (-)	- (-)	1.3 (0.6)	1.3 (0.6)	1.3 (0.5)
			Min	-	-	1	1	1
			Median	-	-	1.0	1.0	1.0
			Max	-	-	2	2	2
	Myalgia	Time from dose to first systemic reaction [Days]	n	4	5	6	15	48
			Mean (SD)	1.0 (0.0)	2.2 (1.6)	1.2 (0.4)	1.5 (1.1)	1.3 (0.7)
			Min	1	1	1	1	1
			Median	1.0	2.0	1.0	1.0	1.0
			Max	1	5	2	5	5
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	1	1	2	7
			Mean (SD)	- (-)	2.0 (-)	1.0 (-)	1.5 (-)	1.4 (0.5)
			Min	-	2	1	1	1
			Median	-	2.0	1.0	1.5	1.0
			Max	-	2	1	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After boost	Myalgia	Time from first systemic reaction to last systemic reaction [Days]	n	4	5	6	15	48
			Mean (SD)	2.8 (1.0)	2.8 (0.8)	3.2 (1.5)	2.9 (1.1)	2.7 (1.4)
			Min	2	2	2	2	1
			Median	2.5	3.0	3.0	3.0	2.0
			Max	4	4	6	6	7
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	1	1	2	7
			Mean (SD)	- (-)	1.0 (-)	1.0 (-)	1.0 (-)	1.0 (0.0)
			Min	-	1	1	1	1
			Median	-	1.0	1.0	1.0	1.0
			Max	-	1	1	1	1
	Arthralgia	Time from dose to first systemic reaction [Days]	n	3	5	6	14	35
			Mean (SD)	1.0 (0.0)	1.4 (0.5)	1.3 (0.5)	1.3 (0.5)	1.3 (0.5)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	1	2	2	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

Program: Tsaf_sysR_5.sas (Page 53 of 60)

Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After boost	Arthralgia	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	1	1	2	5
			Mean (SD)	- (-)	2.0 (-)	2.0 (-)	2.0 (-)	1.4 (0.5)
			Min	-	2	2	2	1
			Median	-	2.0	2.0	2.0	1.0
			Max	-	2	2	2	2
		Time from first systemic reaction to last systemic reaction [Days]	n	3	5	6	14	35
			Mean (SD)	2.7 (1.5)	2.2 (0.8)	2.3 (2.3)	2.4 (1.6)	2.3 (1.4)
			Min	1	1	1	1	1
			Median	3.0	2.0	1.5	2.0	2.0
			Max	4	3	7	7	7
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	1	1	2	5
			Mean (SD)	- (-)	1.0 (-)	1.0 (-)	1.0 (-)	1.0 (0.0)
			Min	-	1	1	1	1
			Median	-	1.0	1.0	1.0	1.0
			Max	-	1	1	1	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After boost	Chills	Time from dose to first systemic reaction [Days]	n	3	5	7	15	48
			Mean (SD)	1.0 (0.0)	1.4 (0.5)	1.0 (0.0)	1.1 (0.4)	1.2 (0.5)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	1	2	1	2	3
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	1	1	1	3	15
			Mean (SD)	1.0 (-)	1.0 (-)	1.0 (-)	1.0 (0.0)	1.1 (0.3)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	1	1	1	1	2
		Time from first systemic reaction to last systemic reaction [Days]	n	3	5	7	15	48
			Mean (SD)	2.0 (1.0)	1.8 (0.8)	1.7 (0.8)	1.8 (0.8)	1.8 (0.8)
			Min	1	1	1	1	1
			Median	2.0	2.0	2.0	2.0	2.0
			Max	3	3	3	3	5

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After boost	Chills	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	1	1	1	3	15
			Mean (SD)	1.0 (-)	1.0 (-)	1.0 (-)	1.0 (0.0)	1.2 (0.4)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	1	1	1	1	2
	Loss of Appetite	Time from dose to first systemic reaction [Days]	n	1	3	6	10	35
			Mean (SD)	2.0 (-)	1.3 (0.6)	1.3 (0.5)	1.4 (0.5)	1.5 (0.5)
			Min	2	1	1	1	1
			Median	2.0	1.0	1.0	1.0	1.0
			Max	2	2	2	2	2
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	8
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.4 (0.7)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After boost	Loss of Appetite	Time from first systemic reaction to last systemic reaction [Days]	n	1	3	6	10	35
			Mean (SD)	1.0 (-)	3.7 (1.5)	2.5 (2.3)	2.7 (2.1)	2.3 (1.7)
			Min	1	2	1	1	1
			Median	1.0	4.0	1.5	2.0	2.0
			Max	1	5	7	7	7
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	8
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.6 (0.5)
			Min	-	-	-	-	1
			Median	-	-	-	-	2.0
			Max	-	-	-	-	2
	Malaise	Time from dose to first systemic reaction [Days]	n	4	6	6	16	51
			Mean (SD)	1.5 (0.6)	1.7 (0.5)	1.2 (0.4)	1.4 (0.5)	1.3 (0.5)
			Min	1	1	1	1	1
			Median	1.5	2.0	1.0	1.0	1.0
			Max	2	2	2	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

Program: Tsaf_sysR_5.sas (Page 57 of 60)

Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After boost	Malaise	Time from dose to first systemic reaction with grade >= 3 [Days]	n	1	0	0	1	12
			Mean (SD)	1.0 (-)	- (-)	- (-)	1.0 (-)	1.0 (0.0)
			Min	1	-	-	1	1
			Median	1.0	-	-	1.0	1.0
			Max	1	-	-	1	1
		Time from first systemic reaction to last systemic reaction [Days]	n	4	6	6	16	51
			Mean (SD)	2.3 (1.0)	1.7 (0.8)	2.0 (0.6)	1.9 (0.8)	2.5 (1.5)
			Min	1	1	1	1	1
			Median	2.5	1.5	2.0	2.0	2.0
			Max	3	3	3	3	7
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	1	0	0	1	12
			Mean (SD)	2.0 (-)	- (-)	- (-)	2.0 (-)	1.7 (0.7)
			Min	2	-	-	2	1
			Median	2.0	-	-	2.0	2.0
			Max	2	-	-	2	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After boost	Fever	Time from dose to first systemic reaction [Days]	n	2	1	5	8	29
			Mean (SD)	1.0 (-)	2.0 (-)	1.4 (0.5)	1.4 (0.5)	1.3 (0.5)
			Min	1	2	1	1	1
			Median	1.0	2.0	1.0	1.0	1.0
			Max	1	2	2	2	2
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	7
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.1 (0.4)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	2
		Time from first systemic reaction to last systemic reaction [Days]	n	2	1	5	8	29
			Mean (SD)	1.5 (-)	1.0 (-)	1.0 (0.0)	1.1 (0.4)	1.3 (0.5)
			Min	1	1	1	1	1
			Median	1.5	1.0	1.0	1.0	1.0
			Max	2	1	1	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-1: Descriptive statistics of time of solicited systemic reactions by term - BNT162b1

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
After boost	Fever	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	7
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (0.0)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.6.1-1: Frequency of subjects with solicited systemic reactions per day - BNT162b1

Safety set

		Younger dose ranging cohorts							
	Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Any n	9	8	8	11	11	12	12	71
	Day 0 n (%)	9 (100)	5 (63)	6 (75)	10 (91)	10 (91)	10 (83)	11 (92)	61 (86)
	Day 1 n (%)	2 (22)	3 (38)	5 (63)	9 (82)	10 (91)	12 (100)	12 (100)	53 (75)
	Day 2 n (%)	1 (11)	3 (38)	3 (38)	5 (45)	4 (36)	7 (58)	4 (33)	27 (38)
	Day 3 n (%)	1 (11)	2 (25)	2 (25)	3 (27)	4 (36)	5 (42)	3 (25)	20 (28)
	Day 4 n (%)	0 (0)	1 (13)	3 (38)	2 (18)	2 (18)	3 (25)	1 (8)	12 (17)
	Day 5 n (%)	3 (33)	1 (13)	2 (25)	3 (27)	3 (27)	2 (17)	0 (0)	14 (20)
	Day 6 n (%)	1 (11)	2 (25)	1 (13)	1 (9)	1 (9)	1 (8)	1 (8)	8 (11)
	Day 7 n (%)	0 (0)	1 (13)	1 (13)	0 (0)	0 (0)	0 (0)	0 (0)	2 (3)
	Day missing n	0	0	1	0	0	0	0	1
After boost	Any n	7	7	9	10	11	11	N/A	55
	Day 0 n (%)	5 (71)	6 (86)	8 (89)	9 (90)	11 (100)	10 (91)	N/A	49 (89)
	Day 1 n (%)	6 (86)	3 (43)	8 (89)	10 (100)	11 (100)	10 (91)	N/A	48 (87)
	Day 2 n (%)	3 (43)	3 (43)	5 (56)	8 (80)	5 (45)	6 (55)	N/A	30 (55)
	Day 3 n (%)	3 (43)	1 (14)	2 (22)	5 (50)	5 (45)	5 (45)	N/A	21 (38)
	Day 4 n (%)	4 (57)	2 (29)	2 (22)	3 (30)	1 (9)	1 (9)	N/A	13 (24)
	Day 5 n (%)	2 (29)	3 (43)	2 (22)	3 (30)	1 (9)	1 (9)	N/A	12 (22)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 1 of 4)

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.1-2.6.1-1: Frequency of subjects with solicited systemic reactions per day - BNT162b1

Safety set

		Younger dose ranging cohorts							
	Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Day 6 n (%)	0 (0)	0 (0)	2 (22)	1 (10)	1 (9)	0 (0)	N/A	4 (7)
	Day 7 n (%)	0 (0)	0 (0)	2 (22)	0 (0)	0 (0)	0 (0)	N/A	2 (4)
	Day missing n	0	0	1	0	0	0	N/A	1

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 2 of 4)

Table 14.3.1-2.6.1-1: Frequency of subjects with solicited systemic reactions per day - BNT162b1

Safety set

		Older dose ranging cohorts				
	Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=31)	Total (N=120)
After prime	Any n	9	11	11	31	10
	Day 0 n (%)	5 (56)	6 (55)	7 (64)	18 (58)	79 (77)
	Day 1 n (%)	7 (78)	9 (82)	10 (91)	26 (84)	79 (77)
	Day 2 n (%)	3 (33)	6 (55)	6 (55)	15 (48)	42 (41)
	Day 3 n (%)	2 (22)	3 (27)	2 (18)	7 (23)	27 (26)
	Day 4 n (%)	1 (11)	2 (18)	1 (9)	4 (13)	16 (16)
	Day 5 n (%)	0 (0)	1 (9)	1 (9)	2 (6)	16 (16)
	Day 6 n (%)	1 (11)	0 (0)	2 (18)	3 (10)	11 (11)
	Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day missing n	0	0	0	0	1
After boost	Any n	8	10	12	30	85
	Day 0 n (%)	6 (75)	6 (60)	10 (83)	22 (73)	71 (84)
	Day 1 n (%)	7 (88)	9 (90)	11 (92)	27 (90)	75 (88)
	Day 2 n (%)	4 (50)	6 (60)	8 (67)	18 (60)	48 (56)
	Day 3 n (%)	2 (25)	4 (40)	1 (8)	7 (23)	28 (33)
	Day 4 n (%)	1 (13)	1 (10)	2 (17)	4 (13)	17 (20)
	Day 5 n (%)	1 (13)	1 (10)	2 (17)	4 (13)	16 (19)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 3 of 4)

Table 14.3.1-2.6.1-1: Frequency of subjects with solicited systemic reactions per day - BNT162b1

Safety set

		Older dose ranging cohorts				
	Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=31)	Total (N=120)
After boost	Day 6 n (%)	0 (0)	1 (10)	2 (17)	3 (10)	7 (8)
	Day 7 n (%)	0 (0)	1 (10)	0 (0)	1 (3)	3 (4)
	Day missing n	0	0	0	0	1

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 4 of 4)

Table 14.3.1-2.6.2-1: Frequency of subjects with solicited systemic reactions by term per day - BNT162b1

Safety set

			Younger dose ranging cohorts							
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Nausea	Any n	1	0	1	4	1	4	4	15
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	2 (50)	1 (100)	2 (50)	3 (75)	8 (53)
		Day 1 n (%)	0 (0)	0 (0)	1 (100)	2 (50)	0 (0)	4 (100)	2 (50)	9 (60)
		Day 2 n (%)	0 (0)	0 (0)	1 (100)	2 (50)	0 (0)	2 (50)	0 (0)	5 (33)
		Day 3 n (%)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	1 (25)	0 (0)	2 (13)
		Day 4 n (%)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	1 (7)
		Day 6 n (%)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (7)
		Day 7 n (%)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	1 (7)
	Vomiting	Any n	0	0	0	0	0	1	1	2
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	1 (100)	2 (100)
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Diarrhea	Any n	1	1	2	0	1	1	1	7
		Day 0 n (%)	1 (100)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	2 (29)
		Day 1 n (%)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)
		Day 2 n (%)	0 (0)	1 (100)	2 (100)	0 (0)	0 (0)	1 (100)	0 (0)	4 (57)
		Day 3 n (%)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	1 (100)	2 (29)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	1 (14)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 1 of 20)

Table 14.3.1-2.6.2-1: Frequency of subjects with solicited systemic reactions by term per day - BNT162b1

Safety set

			Younger dose ranging cohorts							
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Diarrhea	Day 6 n (%)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)
		Day 7 n (%)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)
	Headache	Any n	5	6	5	6	10	10	8	50
		Day 0 n (%)	3 (60)	4 (67)	3 (60)	5 (83)	9 (90)	7 (70)	7 (88)	38 (76)
		Day 1 n (%)	0 (0)	1 (17)	4 (80)	5 (83)	7 (70)	10 (100)	7 (88)	34 (68)
		Day 2 n (%)	0 (0)	1 (17)	2 (40)	2 (33)	3 (30)	4 (40)	2 (25)	14 (28)
		Day 3 n (%)	0 (0)	2 (33)	2 (40)	1 (17)	3 (30)	2 (20)	1 (13)	11 (22)
		Day 4 n (%)	0 (0)	0 (0)	2 (40)	0 (0)	1 (10)	1 (10)	1 (13)	5 (10)
		Day 5 n (%)	2 (40)	0 (0)	2 (40)	1 (17)	1 (10)	2 (20)	0 (0)	8 (16)
		Day 6 n (%)	1 (20)	1 (17)	1 (20)	0 (0)	1 (10)	0 (0)	1 (13)	5 (10)
		Day 7 n (%)	0 (0)	0 (0)	1 (20)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
		Day missing n	0	0	1	0	0	0	0	1
	Fatigue	Any n	8	6	6	11	8	12	11	62
		Day 0 n (%)	7 (88)	5 (83)	4 (67)	8 (73)	7 (88)	7 (58)	10 (91)	48 (77)
		Day 1 n (%)	2 (25)	3 (50)	3 (50)	8 (73)	5 (63)	8 (67)	7 (64)	36 (58)
		Day 2 n (%)	1 (13)	3 (50)	2 (33)	5 (45)	2 (25)	4 (33)	2 (18)	19 (31)
		Day 3 n (%)	1 (13)	1 (17)	2 (33)	1 (9)	2 (25)	4 (33)	1 (9)	12 (19)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 2 of 20)

Table 14.3.1-2.6.2-1: Frequency of subjects with solicited systemic reactions by term per day - BNT162b1

Safety set

			Younger dose ranging cohorts							
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Fatigue	Day 4 n (%)	0 (0)	0 (0)	3 (50)	1 (9)	1 (13)	3 (25)	0 (0)	8 (13)
		Day 5 n (%)	2 (25)	0 (0)	1 (17)	2 (18)	1 (13)	0 (0)	0 (0)	6 (10)
		Day 6 n (%)	1 (13)	0 (0)	1 (17)	1 (9)	0 (0)	1 (8)	1 (9)	5 (8)
		Day 7 n (%)	0 (0)	0 (0)	1 (17)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
	Myalgia	Any n	1	0	2	6	6	7	11	33
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	4 (67)	6 (100)	3 (43)	9 (82)	22 (67)
		Day 1 n (%)	0 (0)	0 (0)	2 (100)	4 (67)	4 (67)	5 (71)	10 (91)	25 (76)
		Day 2 n (%)	0 (0)	0 (0)	1 (50)	2 (33)	0 (0)	3 (43)	4 (36)	10 (30)
		Day 3 n (%)	0 (0)	0 (0)	1 (50)	1 (17)	0 (0)	1 (14)	2 (18)	5 (15)
		Day 4 n (%)	0 (0)	0 (0)	1 (50)	1 (17)	0 (0)	0 (0)	0 (0)	2 (6)
		Day 5 n (%)	1 (100)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	2 (6)
		Day 6 n (%)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)
		Day 7 n (%)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)
	Arthralgia	Any n	0	0	1	3	4	5	5	18
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	4 (100)	1 (20)	3 (60)	8 (44)
		Day 1 n (%)	0 (0)	0 (0)	1 (100)	3 (100)	4 (100)	5 (100)	3 (60)	16 (89)
		Day 2 n (%)	0 (0)	0 (0)	1 (100)	1 (33)	0 (0)	2 (40)	1 (20)	5 (28)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 3 of 20)

Table 14.3.1-2.6.2-1: Frequency of subjects with solicited systemic reactions by term per day - BNT162b1

Safety set

			Younger dose ranging cohorts							
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Arthralgia	Day 3 n (%)	0 (0)	0 (0)	1 (100)	1 (33)	0 (0)	0 (0)	1 (20)	3 (17)
		Day 4 n (%)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)
		Day 5 n (%)	0 (0)	0 (0)	1 (100)	1 (33)	0 (0)	0 (0)	0 (0)	2 (11)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Chills	Any n	2	1	1	4	4	10	10	32
		Day 0 n (%)	1 (50)	0 (0)	0 (0)	3 (75)	3 (75)	2 (20)	10 (100)	19 (59)
		Day 1 n (%)	0 (0)	1 (100)	1 (100)	3 (75)	1 (25)	10 (100)	5 (50)	21 (66)
		Day 2 n (%)	0 (0)	1 (100)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	2 (6)
		Day 3 n (%)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)
		Day 4 n (%)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)
		Day 5 n (%)	1 (50)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (6)
		Day 6 n (%)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)
		Day 7 n (%)	0 (0)	1 (100)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	2 (6)
	Loss of Appetite	Any n	0	0	2	3	3	7	6	21
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	2 (67)	1 (33)	1 (14)	5 (83)	9 (43)
		Day 1 n (%)	0 (0)	0 (0)	1 (50)	2 (67)	2 (67)	7 (100)	4 (67)	16 (76)
		Day 2 n (%)	0 (0)	0 (0)	1 (50)	2 (67)	0 (0)	5 (71)	0 (0)	8 (38)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 4 of 20)

Table 14.3.1-2.6.2-1: Frequency of subjects with solicited systemic reactions by term per day - BNT162b1

Safety set

			Younger dose ranging cohorts							
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Loss of Appetite	Day 3 n (%)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	2 (29)	0 (0)	3 (14)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	1 (5)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (14)	0 (0)	1 (5)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Day 7 n (%)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)
		Day missing n	0	0	1	0	0	0	0	1
	Malaise	Any n	2	0	2	6	8	10	9	37
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	6 (100)	5 (63)	6 (60)	7 (78)	24 (65)
		Day 1 n (%)	0 (0)	0 (0)	1 (50)	4 (67)	6 (75)	9 (90)	6 (67)	26 (70)
		Day 2 n (%)	0 (0)	0 (0)	1 (50)	2 (33)	1 (13)	4 (40)	2 (22)	10 (27)
		Day 3 n (%)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	2 (20)	0 (0)	3 (8)
		Day 4 n (%)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	2 (20)	0 (0)	3 (8)
		Day 5 n (%)	2 (100)	0 (0)	1 (50)	0 (0)	1 (13)	1 (10)	0 (0)	5 (14)
		Day 6 n (%)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	1 (10)	0 (0)	2 (5)
		Day 7 n (%)	0 (0)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)
		Day missing n	0	0	1	0	0	0	0	1
	Fever	Any n	0	0	0	0	1	4	4	9

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 5 of 20)

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.1-2.6.2-1: Frequency of subjects with solicited systemic reactions by term per day - BNT162b1

Safety set

			Younger dose ranging cohorts							
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After prime	Fever	Day 0 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	4 (100)	5 (56)
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	4 (100)	1 (25)	5 (56)
After boost	Nausea	Any n	2	1	3	3	3	4	N/A	16
		Day 0 n (%)	1 (50)	0 (0)	2 (67)	3 (100)	2 (67)	4 (100)	N/A	12 (75)
		Day 1 n (%)	2 (100)	1 (100)	2 (67)	1 (33)	2 (67)	2 (50)	N/A	10 (63)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	1 (33)	1 (33)	1 (25)	N/A	3 (19)
		Day 3 n (%)	1 (50)	0 (0)	0 (0)	1 (33)	0 (0)	1 (25)	N/A	3 (19)
		Day 4 n (%)	2 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	2 (13)
	Vomiting	Any n	0	0	0	1	0	1	N/A	2
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	1 (100)	N/A	2 (100)
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	N/A	1 (50)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	N/A	1 (50)
	Diarrhea	Any n	0	0	0	1	0	1	N/A	2
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	N/A	1 (50)
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	1 (100)	N/A	2 (100)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	N/A	1 (50)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	N/A	1 (50)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 6 of 20)

Table 14.3.1-2.6.2-1: Frequency of subjects with solicited systemic reactions by term per day - BNT162b1

Safety set

			Younger dose ranging cohorts							
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Headache	Any n	7	6	8	9	10	9	N/A	49
		Day 0 n (%)	5 (71)	4 (67)	7 (88)	8 (89)	10 (100)	8 (89)	N/A	42 (86)
		Day 1 n (%)	5 (71)	3 (50)	5 (63)	9 (100)	10 (100)	8 (89)	N/A	40 (82)
		Day 2 n (%)	2 (29)	2 (33)	3 (38)	6 (67)	4 (40)	5 (56)	N/A	22 (45)
		Day 3 n (%)	1 (14)	1 (17)	1 (13)	3 (33)	3 (30)	1 (11)	N/A	10 (20)
		Day 4 n (%)	2 (29)	1 (17)	1 (13)	1 (11)	0 (0)	0 (0)	N/A	5 (10)
		Day 5 n (%)	1 (14)	1 (17)	1 (13)	1 (11)	0 (0)	0 (0)	N/A	4 (8)
		Day 6 n (%)	0 (0)	0 (0)	1 (13)	0 (0)	1 (10)	0 (0)	N/A	2 (4)
		Day 7 n (%)	0 (0)	0 (0)	1 (13)	0 (0)	0 (0)	0 (0)	N/A	1 (2)
		Day missing n	0	0	1	0	0	0	N/A	1
	Fatigue	Any n	5	6	6	6	10	9	N/A	42
		Day 0 n (%)	3 (60)	5 (83)	6 (100)	5 (83)	8 (80)	9 (100)	N/A	36 (86)
		Day 1 n (%)	4 (80)	3 (50)	6 (100)	4 (67)	8 (80)	8 (89)	N/A	33 (79)
		Day 2 n (%)	3 (60)	3 (50)	3 (50)	4 (67)	2 (20)	4 (44)	N/A	19 (45)
		Day 3 n (%)	2 (40)	1 (17)	1 (17)	3 (50)	2 (20)	2 (22)	N/A	11 (26)
		Day 4 n (%)	2 (40)	2 (33)	1 (17)	3 (50)	1 (10)	0 (0)	N/A	9 (21)
		Day 5 n (%)	1 (20)	2 (33)	1 (17)	1 (17)	0 (0)	1 (11)	N/A	6 (14)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

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Table 14.3.1-2.6.2-1: Frequency of subjects with solicited systemic reactions by term per day - BNT162b1

Safety set

			Younger dose ranging cohorts							
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Fatigue	Day 6 n (%)	0 (0)	0 (0)	1 (17)	0 (0)	0 (0)	0 (0)	N/A	1 (2)
		Day 7 n (%)	0 (0)	0 (0)	1 (17)	0 (0)	0 (0)	0 (0)	N/A	1 (2)
	Myalgia	Any n	5	2	6	5	9	6	N/A	33
		Day 0 n (%)	3 (60)	1 (50)	3 (50)	4 (80)	8 (89)	6 (100)	N/A	25 (76)
		Day 1 n (%)	3 (60)	2 (100)	6 (100)	5 (100)	8 (89)	5 (83)	N/A	29 (88)
		Day 2 n (%)	1 (20)	1 (50)	3 (50)	4 (80)	3 (33)	4 (67)	N/A	16 (48)
		Day 3 n (%)	1 (20)	1 (50)	1 (17)	1 (20)	2 (22)	3 (50)	N/A	9 (27)
		Day 4 n (%)	1 (20)	1 (50)	1 (17)	1 (20)	0 (0)	0 (0)	N/A	4 (12)
		Day 5 n (%)	1 (20)	0 (0)	0 (0)	1 (20)	0 (0)	0 (0)	N/A	2 (6)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	1 (20)	0 (0)	0 (0)	N/A	1 (3)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
	Arthralgia	Any n	2	1	3	1	8	6	N/A	21
		Day 0 n (%)	0 (0)	0 (0)	1 (33)	1 (100)	7 (88)	6 (100)	N/A	15 (71)
		Day 1 n (%)	2 (100)	1 (100)	3 (100)	1 (100)	7 (88)	5 (83)	N/A	19 (90)
		Day 2 n (%)	0 (0)	0 (0)	1 (33)	1 (100)	2 (25)	3 (50)	N/A	7 (33)
		Day 3 n (%)	1 (50)	0 (0)	0 (0)	1 (100)	0 (0)	2 (33)	N/A	4 (19)
		Day 4 n (%)	1 (50)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	N/A	2 (10)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 8 of 20)

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.1-2.6.2-1: Frequency of subjects with solicited systemic reactions by term per day - BNT162b1

Safety set

			Younger dose ranging cohorts							
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Arthralgia	Day 5 n (%)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (5)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
	Chills	Any n	4	1	5	5	9	9	N/A	33
		Day 0 n (%)	2 (50)	0 (0)	4 (80)	4 (80)	7 (78)	8 (89)	N/A	25 (76)
		Day 1 n (%)	2 (50)	0 (0)	5 (100)	3 (60)	7 (78)	7 (78)	N/A	24 (73)
		Day 2 n (%)	0 (0)	1 (100)	0 (0)	2 (40)	1 (11)	1 (11)	N/A	5 (15)
		Day 3 n (%)	0 (0)	1 (100)	0 (0)	1 (20)	0 (0)	0 (0)	N/A	2 (6)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	1 (20)	0 (0)	0 (0)	N/A	1 (3)
	Loss of Appetite	Any n	2	1	6	4	5	8	N/A	26
		Day 0 n (%)	2 (100)	0 (0)	1 (17)	3 (75)	1 (20)	6 (75)	N/A	13 (50)
		Day 1 n (%)	2 (100)	1 (100)	5 (83)	4 (100)	4 (80)	7 (88)	N/A	23 (88)
		Day 2 n (%)	2 (100)	0 (0)	0 (0)	3 (75)	0 (0)	3 (38)	N/A	8 (31)
		Day 3 n (%)	2 (100)	0 (0)	0 (0)	1 (25)	0 (0)	3 (38)	N/A	6 (23)
		Day 4 n (%)	2 (100)	0 (0)	0 (0)	1 (25)	0 (0)	1 (13)	N/A	4 (15)
		Day 5 n (%)	1 (50)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (4)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
		Day missing n	0	0	1	0	0	0	N/A	1

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 9 of 20)

Table 14.3.1-2.6.2-1: Frequency of subjects with solicited systemic reactions by term per day - BNT162b1

Safety set

			Younger dose ranging cohorts							
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
After boost	Malaise	Any n	2	2	6	5	10	10	N/A	35
		Day 0 n (%)	2 (100)	1 (50)	2 (33)	3 (60)	8 (80)	9 (90)	N/A	25 (71)
		Day 1 n (%)	2 (100)	2 (100)	6 (100)	4 (80)	10 (100)	9 (90)	N/A	33 (94)
		Day 2 n (%)	2 (100)	1 (50)	1 (17)	4 (80)	3 (30)	4 (40)	N/A	15 (43)
		Day 3 n (%)	2 (100)	0 (0)	0 (0)	2 (40)	3 (30)	1 (10)	N/A	8 (23)
		Day 4 n (%)	2 (100)	0 (0)	1 (17)	1 (20)	1 (10)	0 (0)	N/A	5 (14)
		Day 5 n (%)	1 (50)	1 (50)	0 (0)	0 (0)	1 (10)	0 (0)	N/A	3 (9)
		Day 6 n (%)	0 (0)	0 (0)	1 (17)	0 (0)	1 (10)	0 (0)	N/A	2 (6)
		Day missing n	0	0	1	0	0	0	N/A	1
	Fever	Any n	1	1	4	4	5	6	N/A	21
		Day 0 n (%)	1 (100)	0 (0)	3 (75)	3 (75)	3 (60)	4 (67)	N/A	14 (67)
		Day 1 n (%)	0 (0)	1 (100)	2 (50)	3 (75)	2 (40)	6 (100)	N/A	14 (67)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 10 of 20)

Table 14.3.1-2.6.2-1: Frequency of subjects with solicited systemic reactions by term per day - BNT162b1

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=31)	Total (N=120)
After prime	Nausea	Any n	1	1	2	4	19
		Day 0 n (%)	0 (0)	0 (0)	1 (50)	1 (25)	9 (47)
		Day 1 n (%)	1 (100)	0 (0)	1 (50)	2 (50)	11 (58)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	5 (26)
		Day 3 n (%)	0 (0)	1 (100)	0 (0)	1 (25)	3 (16)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)
	Vomiting	Any n	1	0	0	1	3
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (67)
		Day 1 n (%)	1 (100)	0 (0)	0 (0)	1 (100)	1 (33)
	Diarrhea	Any n	0	2	1	3	1
		Day 0 n (%)	0 (0)	2 (100)	1 (100)	3 (100)	5 (50)
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	4 (40)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (20)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 11 of 20)

Table 14.3.1-2.6.2-1: Frequency of subjects with solicited systemic reactions by term per day - BNT162b1

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=31)	Total (N=120)
After prime	Diarrhea	Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)
	Headache	Any n	8	6	4	18	68
		Day 0 n (%)	4 (50)	1 (17)	3 (75)	8 (44)	46 (68)
		Day 1 n (%)	6 (75)	4 (67)	4 (100)	14 (78)	48 (71)
		Day 2 n (%)	2 (25)	3 (50)	0 (0)	5 (28)	19 (28)
		Day 3 n (%)	1 (13)	1 (17)	0 (0)	2 (11)	13 (19)
		Day 4 n (%)	1 (13)	1 (17)	0 (0)	2 (11)	7 (10)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	8 (12)
		Day 6 n (%)	1 (13)	0 (0)	0 (0)	1 (6)	6 (9)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Day missing n	0	0	0	0	1
	Fatigue	Any n	6	7	9	22	84
		Day 0 n (%)	3 (50)	3 (43)	5 (56)	11 (50)	59 (70)
		Day 1 n (%)	3 (50)	7 (100)	8 (89)	18 (82)	54 (64)
		Day 2 n (%)	1 (17)	2 (29)	3 (33)	6 (27)	25 (30)
		Day 3 n (%)	1 (17)	1 (14)	1 (11)	3 (14)	15 (18)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 12 of 20)

Table 14.3.1-2.6.2-1: Frequency of subjects with solicited systemic reactions by term per day - BNT162b1

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=31)	Total (N=120)
After prime	Fatigue	Day 4 n (%)	1 (17)	1 (14)	0 (0)	2 (9)	10 (12)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	6 (7)
		Day 6 n (%)	0 (0)	0 (0)	1 (11)	1 (5)	6 (7)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Myalgia	Any n	2	5	7	14	47
		Day 0 n (%)	1 (50)	2 (40)	3 (43)	6 (43)	28 (60)
		Day 1 n (%)	2 (100)	4 (80)	5 (71)	11 (79)	36 (77)
		Day 2 n (%)	0 (0)	3 (60)	3 (43)	6 (43)	16 (34)
		Day 3 n (%)	0 (0)	2 (40)	0 (0)	2 (14)	7 (15)
		Day 4 n (%)	0 (0)	1 (20)	1 (14)	2 (14)	4 (9)
		Day 5 n (%)	0 (0)	1 (20)	0 (0)	1 (7)	3 (6)
		Day 6 n (%)	0 (0)	0 (0)	1 (14)	1 (7)	2 (4)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
	Arthralgia	Any n	1	3	4	8	26
		Day 0 n (%)	0 (0)	0 (0)	1 (25)	1 (13)	9 (35)
		Day 1 n (%)	1 (100)	3 (100)	4 (100)	8 (100)	24 (92)
		Day 2 n (%)	0 (0)	2 (67)	2 (50)	4 (50)	9 (35)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 13 of 20)

Table 14.3.1-2.6.2-1: Frequency of subjects with solicited systemic reactions by term per day - BNT162b1

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=31)	Total (N=120)
After prime	Arthralgia	Day 3 n (%)	0 (0)	1 (33)	1 (25)	2 (25)	5 (19)
		Day 4 n (%)	0 (0)	1 (33)	1 (25)	2 (25)	3 (12)
		Day 5 n (%)	0 (0)	0 (0)	1 (25)	1 (13)	3 (12)
		Day 6 n (%)	0 (0)	0 (0)	1 (25)	1 (13)	1 (4)
	Chills	Any n	1	3	3	7	39
		Day 0 n (%)	0 (0)	0 (0)	1 (33)	1 (14)	20 (51)
		Day 1 n (%)	1 (100)	2 (67)	2 (67)	5 (71)	26 (67)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (5)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)
		Day 4 n (%)	0 (0)	1 (33)	1 (33)	2 (29)	3 (8)
		Day 5 n (%)	0 (0)	0 (0)	1 (33)	1 (14)	3 (8)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (5)
	Loss of Appetite	Any n	1	0	2	3	24
		Day 0 n (%)	0 (0)	0 (0)	1 (50)	1 (33)	10 (42)
		Day 1 n (%)	1 (100)	0 (0)	1 (50)	2 (67)	18 (75)
		Day 2 n (%)	0 (0)	0 (0)	1 (50)	1 (33)	9 (38)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 14 of 20)

Table 14.3.1-2.6.2-1: Frequency of subjects with solicited systemic reactions by term per day - BNT162b1

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=31)	Total (N=120)
After prime	Loss of Appetite	Day 3 n (%)	1 (100)	0 (0)	1 (50)	2 (67)	5 (21)
		Day 4 n (%)	0 (0)	0 (0)	1 (50)	1 (33)	2 (8)
		Day 5 n (%)	0 (0)	0 (0)	1 (50)	1 (33)	2 (8)
		Day 6 n (%)	0 (0)	0 (0)	1 (50)	1 (33)	1 (4)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (4)
		Day missing n	0	0	0	0	1
	Malaise	Any n	3	1	4	8	45
		Day 0 n (%)	1 (33)	0 (0)	1 (25)	2 (25)	26 (58)
		Day 1 n (%)	2 (67)	0 (0)	4 (100)	6 (75)	32 (71)
		Day 2 n (%)	0 (0)	0 (0)	1 (25)	1 (13)	11 (24)
		Day 3 n (%)	0 (0)	1 (100)	0 (0)	1 (13)	4 (9)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (7)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	5 (11)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
		Day missing n	0	0	0	0	1
	Fever	Any n	0	0	0	0	9

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 15 of 20)

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.1-2.6.2-1: Frequency of subjects with solicited systemic reactions by term per day - BNT162b1

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=31)	Total (N=120)
After prime	Fever	Day 0 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	5 (56)
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	5 (56)
After boost	Nausea	Any n	1	2	4	7	23
		Day 0 n (%)	1 (100)	1 (50)	3 (75)	5 (71)	17 (74)
		Day 1 n (%)	0 (0)	1 (50)	3 (75)	4 (57)	14 (61)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (13)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (13)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (9)
	Vomiting	Any n	1	0	1	2	4
		Day 0 n (%)	1 (100)	0 (0)	1 (100)	2 (100)	4 (100)
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (25)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (25)
	Diarrhea	Any n	0	0	0	0	2
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (50)
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (100)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (50)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (50)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 16 of 20)

Table 14.3.1-2.6.2-1: Frequency of subjects with solicited systemic reactions by term per day - BNT162b1

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=31)	Total (N=120)
After boost	Headache	Any n	8	9	10	27	76
		Day 0 n (%)	5 (63)	3 (33)	8 (80)	16 (59)	58 (76)
		Day 1 n (%)	6 (75)	8 (89)	8 (80)	22 (81)	62 (82)
		Day 2 n (%)	4 (50)	2 (22)	1 (10)	7 (26)	29 (38)
		Day 3 n (%)	1 (13)	0 (0)	0 (0)	1 (4)	11 (14)
		Day 4 n (%)	1 (13)	0 (0)	0 (0)	1 (4)	6 (8)
		Day 5 n (%)	1 (13)	0 (0)	0 (0)	1 (4)	5 (7)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (3)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Day missing n	0	0	0	0	1
	Fatigue	Any n	4	7	12	23	65
		Day 0 n (%)	3 (75)	2 (29)	9 (75)	14 (61)	50 (77)
		Day 1 n (%)	2 (50)	5 (71)	9 (75)	16 (70)	49 (75)
		Day 2 n (%)	1 (25)	1 (14)	4 (33)	6 (26)	25 (38)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	11 (17)
		Day 4 n (%)	0 (0)	0 (0)	1 (8)	1 (4)	10 (15)
		Day 5 n (%)	0 (0)	0 (0)	1 (8)	1 (4)	7 (11)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 17 of 20)

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.1-2.6.2-1: Frequency of subjects with solicited systemic reactions by term per day - BNT162b1

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=31)	Total (N=120)
After boost	Fatigue	Day 6 n (%)	0 (0)	0 (0)	1 (8)	1 (4)	2 (3)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
	Myalgia	Any n	4	5	6	15	48
		Day 0 n (%)	3 (75)	2 (40)	5 (83)	10 (67)	35 (73)
		Day 1 n (%)	4 (100)	4 (80)	6 (100)	14 (93)	43 (90)
		Day 2 n (%)	2 (50)	3 (60)	4 (67)	9 (60)	25 (52)
		Day 3 n (%)	1 (25)	1 (20)	0 (0)	2 (13)	11 (23)
		Day 4 n (%)	0 (0)	1 (20)	0 (0)	1 (7)	5 (10)
		Day 5 n (%)	0 (0)	1 (20)	1 (17)	2 (13)	4 (8)
		Day 6 n (%)	0 (0)	1 (20)	0 (0)	1 (7)	2 (4)
		Day 7 n (%)	0 (0)	1 (20)	0 (0)	1 (7)	1 (2)
	Arthralgia	Any n	3	5	5	13	34
		Day 0 n (%)	2 (67)	3 (60)	3 (60)	8 (62)	23 (68)
		Day 1 n (%)	2 (67)	5 (100)	5 (100)	12 (92)	31 (91)
		Day 2 n (%)	1 (33)	2 (40)	1 (20)	4 (31)	11 (32)
		Day 3 n (%)	1 (33)	1 (20)	1 (20)	3 (23)	7 (21)
		Day 4 n (%)	0 (0)	0 (0)	1 (20)	1 (8)	3 (9)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 18 of 20)

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.1-2.6.2-1: Frequency of subjects with solicited systemic reactions by term per day - BNT162b1

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=31)	Total (N=120)
After boost	Arthralgia	Day 5 n (%)	0 (0)	0 (0)	1 (20)	1 (8)	2 (6)
		Day 6 n (%)	0 (0)	0 (0)	1 (20)	1 (8)	1 (3)
	Chills	Any n	3	5	6	14	47
		Day 0 n (%)	2 (67)	3 (60)	6 (100)	11 (79)	36 (77)
		Day 1 n (%)	2 (67)	5 (100)	4 (67)	11 (79)	35 (74)
		Day 2 n (%)	1 (33)	1 (20)	1 (17)	3 (21)	8 (17)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
	Loss of Appetite	Any n	1	3	6	10	36
		Day 0 n (%)	0 (0)	2 (67)	4 (67)	6 (60)	19 (53)
		Day 1 n (%)	1 (100)	3 (100)	5 (83)	9 (90)	32 (89)
		Day 2 n (%)	0 (0)	2 (67)	1 (17)	3 (30)	11 (31)
		Day 3 n (%)	0 (0)	2 (67)	1 (17)	3 (30)	9 (25)
		Day 4 n (%)	0 (0)	1 (33)	1 (17)	2 (20)	6 (17)
		Day 5 n (%)	0 (0)	1 (33)	1 (17)	2 (20)	3 (8)
		Day 6 n (%)	0 (0)	0 (0)	1 (17)	1 (10)	1 (3)
		Day missing n	0	0	0	0	1

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 19 of 20)

Table 14.3.1-2.6.2-1: Frequency of subjects with solicited systemic reactions by term per day - BNT162b1

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=31)	Total (N=120)
After boost	Malaise	Any n	4	6	6	16	51
		Day 0 n (%)	1 (25)	2 (33)	5 (83)	8 (50)	33 (65)
		Day 1 n (%)	4 (100)	5 (83)	6 (100)	15 (94)	48 (94)
		Day 2 n (%)	3 (75)	2 (33)	1 (17)	6 (38)	21 (41)
		Day 3 n (%)	0 (0)	1 (17)	0 (0)	1 (6)	9 (18)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	5 (10)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (6)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)
		Day missing n	0	0	0	0	1
	Fever	Any n	2	1	4	7	28
		Day 0 n (%)	2 (100)	0 (0)	2 (50)	4 (57)	18 (64)
		Day 1 n (%)	1 (50)	1 (100)	2 (50)	4 (57)	18 (64)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 20 of 20)

14.3.1-3 Adverse events

Table 14.3.1-3.1.1-1: Summary of TEAEs - BNT162b1

Safety set

		Younger dose ranging cohorts							
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	50 µg (N=12) n (%) E	60 µg (N=12) n (%) E	Total (N=84) n (%) E
Prime up to Day 7 after prime	Any TEAE	10 (83) 27	1 (8) 1	10 (83) 36	4 (33) 5	11 (92) 41	12 (100) 37	12 (100) 42	60 (71) 189
	Related TEAE	10 (83) 26	0 (0) 0	10 (83) 36	4 (33) 5	11 (92) 41	12 (100) 37	12 (100) 42	59 (70) 187
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	1 (8) 1	1 (1) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	1 (8) 1	1 (1) 1
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Prime up to boost or Day 28 after prime (whatever comes first)	Any TEAE	11 (92) 37	1 (8) 1	10 (83) 48	4 (33) 7	12 (100) 44	12 (100) 43	12 (100) 45	62 (74) 225
	Related TEAE	11 (92) 30	0 (0) 0	10 (83) 38	4 (33) 5	12 (100) 42	12 (100) 40	12 (100) 43	61 (73) 198
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	1 (8) 1	0 (0) 0	0 (0) 0	1 (8) 1	2 (2) 2
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	1 (8) 1	1 (1) 1
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_1.sas (Page 1 of 6)

Table 14.3.1-3.1.1-1: Summary of TEAEs - BNT162b1

Safety set

		Younger dose ranging cohorts							
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	50 µg (N=12) n (%) E	60 µg (N=12) n (%) E	Total (N=84) n (%) E
Boost up to Day 7 after boost	Any TEAE	9 (75) 26	0 (0) 0	11 (92) 23	3 (25) 9	12 (100) 26	11 (92) 39	N/A	46 (55) 123
	Related TEAE	9 (75) 23	0 (0) 0	11 (92) 23	2 (17) 6	12 (100) 26	11 (92) 38	N/A	45 (54) 116
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	2 (17) 5	0 (0) 0	2 (17) 2	N/A	5 (6) 8
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (8) 4	0 (0) 0	2 (17) 2	N/A	4 (5) 7
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	N/A	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	N/A	0 (0) 0
Boost up to Day 28 after boost	Any TEAE	9 (75) 30	0 (0) 0	11 (92) 29	4 (33) 10	12 (100) 32	11 (92) 43	N/A	47 (56) 144
	Related TEAE	9 (75) 23	0 (0) 0	11 (92) 23	2 (17) 6	12 (100) 27	11 (92) 38	N/A	45 (54) 117
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	2 (17) 5	0 (0) 0	2 (17) 2	N/A	5 (6) 8
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (8) 4	0 (0) 0	2 (17) 2	N/A	4 (5) 7
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	N/A	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	N/A	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_1.sas (Page 2 of 6)

Table 14.3.1-3.1.1-1: Summary of TEAEs - BNT162b1

Safety set

		Younger dose ranging cohorts							
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	50 µg (N=12) n (%) E	60 µg (N=12) n (%) E	Total (N=84) n (%) E
Prime up to Day 28 after boost or after prime (if no boost)	Any TEAE	11 (92) 63	1 (8) 1	12 (100) 76	6 (50) 17	12 (100) 75	12 (100) 83	12 (100) 45	66 (79) 360
	Related TEAE	11 (92) 49	0 (0) 0	12 (100) 60	5 (42) 11	12 (100) 68	12 (100) 75	12 (100) 43	64 (76) 306
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	3 (25) 6	0 (0) 0	2 (17) 2	1 (8) 1	7 (8) 10
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (8) 4	0 (0) 0	2 (17) 2	1 (8) 1	5 (6) 8
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_1.sas (Page 3 of 6)

Table 14.3.1-3.1.1-1: Summary of TEAEs - BNT162b1

Safety set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=120) n (%) E
Prime up to Day 7 after prime	Any TEAE	0 (0) 0	0 (0) 0	6 (50) 10	6 (17) 10	66 (55) 199
	Related TEAE	0 (0) 0	0 (0) 0	4 (33) 6	4 (11) 6	63 (53) 193
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	2 (2) 2
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	1 (1) 1
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Prime up to boost or Day 28 after prime (whatever comes first)	Any TEAE	3 (25) 3	2 (17) 4	7 (58) 14	12 (33) 21	74 (62) 246
	Related TEAE	0 (0) 0	0 (0) 0	4 (33) 6	4 (11) 6	65 (54) 204
	Grade >=3 TEAE	1 (8) 1	1 (8) 1	1 (8) 1	3 (8) 3	5 (4) 5
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	1 (1) 1
	Any TESAE	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_1.sas (Page 4 of 6)

Table 14.3.1-3.1.1-1: Summary of TEAEs - BNT162b1

Safety set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=120) n (%) E
Boost up to Day 7 after boost	Any TEAE	0 (0) 0	0 (0) 0	4 (33) 4	4 (11) 4	50 (42) 127
	Related TEAE	0 (0) 0	0 (0) 0	3 (25) 3	3 (8) 3	48 (40) 119
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	6 (5) 9
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	5 (4) 8
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Boost up to Day 28 after boost	Any TEAE	0 (0) 0	0 (0) 0	4 (33) 4	4 (11) 4	51 (43) 148
	Related TEAE	0 (0) 0	0 (0) 0	3 (25) 3	3 (8) 3	48 (40) 120
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	6 (5) 9
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	5 (4) 8
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_1.sas (Page 5 of 6)

Table 14.3.1-3.1.1-1: Summary of TEAEs - BNT162b1

Safety set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=120) n (%) E
Prime up to Day 28 after boost or after prime (if no boost)	Any TEAE	3 (25) 3	2 (17) 4	8 (67) 18	13 (36) 25	79 (66) 385
	Related TEAE	0 (0) 0	0 (0) 0	5 (42) 9	5 (14) 9	69 (58) 315
	Grade >=3 TEAE	1 (8) 1	1 (8) 1	2 (17) 2	4 (11) 4	11 (9) 14
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	6 (5) 9
	Any TESAE	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_1.sas (Page 6 of 6)

Table 14.3.1-3.1.2-1: Summary of TEAEs - completers only - BNT162b1

Prime + 7 Days completers set

		Younger dose ranging cohorts							
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=12) n (%) E	20 µg (N=11) n (%) E	30 µg (N=12) n (%) E	50 µg (N=12) n (%) E	60 µg (N=12) n (%) E	Total (N=83) n (%) E
Prime up to Day 7 after prime	Any TEAE	10 (83) 27	1 (8) 1	10 (83) 36	4 (36) 5	11 (92) 41	12 (100) 37	12 (100) 42	60 (72) 189
	Related TEAE	10 (83) 26	0 (0) 0	10 (83) 36	4 (36) 5	11 (92) 41	12 (100) 37	12 (100) 42	59 (71) 187
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	1 (8) 1	1 (1) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	1 (8) 1	1 (1) 1
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_2.sas (Page 1 of 2)

Table 14.3.1-3.1.2-1: Summary of TEAEs - completers only - BNT162b1

Prime + 7 Days completers set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=119) n (%) E
Prime up to Day 7 after prime	Any TEAE	0 (0) 0	0 (0) 0	6 (50) 10	6 (17) 10	66 (55) 199
	Related TEAE	0 (0) 0	0 (0) 0	4 (33) 6	4 (11) 6	63 (53) 193
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	2 (2) 2
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	1 (1) 1
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_2.sas (Page 2 of 2)

Table 14.3.1-3.1.2-1: Summary of TEAEs - completers only - BNT162b1

Prime to Boost or Prime + 28 Days completers set

		Younger dose ranging cohorts							
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=11) n (%) E	20 µg (N=11) n (%) E	30 µg (N=12) n (%) E	50 µg (N=11) n (%) E	60 µg (N=12) n (%) E	Total (N=81) n (%) E
Prime up to boost or Day 28 after prime (whatever comes first)	Any TEAE	11 (92) 37	1 (8) 1	9 (82) 35	4 (36) 7	12 (100) 44	11 (100) 38	12 (100) 45	60 (74) 207
	Related TEAE	11 (92) 30	0 (0) 0	9 (82) 32	4 (36) 5	12 (100) 42	11 (100) 36	12 (100) 43	59 (73) 188
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	1 (9) 1	0 (0) 0	0 (0) 0	1 (8) 1	2 (2) 2
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	1 (8) 1	1 (1) 1
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_2.sas (Page 1 of 2)

Table 14.3.1-3.1.2-1: Summary of TEAEs - completers only - BNT162b1

Prime to Boost or Prime + 28 Days completers set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=117) n (%) E
Prime up to boost or Day 28 after prime (whatever comes first)	Any TEAE	3 (25) 3	2 (17) 4	7 (58) 14	12 (33) 21	72 (62) 228
	Related TEAE	0 (0) 0	0 (0) 0	4 (33) 6	4 (11) 6	63 (54) 194
	Grade >=3 TEAE	1 (8) 1	1 (8) 1	1 (8) 1	3 (8) 3	5 (4) 5
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	1 (1) 1
	Any TESAE	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_2.sas (Page 2 of 2)

Table 14.3.1-3.1.2-1: Summary of TEAEs - completers only - BNT162b1

Boost + 7 Days completers set

		Younger dose ranging cohorts						
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=11) n (%) E	20 µg (N=11) n (%) E	30 µg (N=12) n (%) E	50 µg (N=11) n (%) E	Total (N=69) n (%) E
Boost up to Day 7 after boost	Any TEAE	9 (75) 26	0 (0) 0	11 (100) 23	3 (27) 9	12 (100) 26	11 (100) 39	46 (67) 123
	Related TEAE	9 (75) 23	0 (0) 0	11 (100) 23	2 (18) 6	12 (100) 26	11 (100) 38	45 (65) 116
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (9) 1	2 (18) 5	0 (0) 0	2 (18) 2	5 (7) 8
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (9) 1	1 (9) 4	0 (0) 0	2 (18) 2	4 (6) 7
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_2.sas (Page 1 of 2)

Table 14.3.1-3.1.2-1: Summary of TEAEs - completers only - BNT162b1

Boost + 7 Days completers set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=11) n (%) E	30 µg (N=12) n (%) E	Total (N=35) n (%) E	Total (N=104) n (%) E
Boost up to Day 7 after boost	Any TEAE	0 (0) 0	0 (0) 0	4 (33) 4	4 (11) 4	50 (48) 127
	Related TEAE	0 (0) 0	0 (0) 0	3 (25) 3	3 (9) 3	48 (46) 119
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	6 (6) 9
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	5 (5) 8
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_2.sas (Page 2 of 2)

Table 14.3.1-3.1.2-1: Summary of TEAEs - completers only - BNT162b1

Boost + 28 Days completers set

		Younger dose ranging cohorts						
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=11) n (%) E	20 µg (N=11) n (%) E	30 µg (N=12) n (%) E	50 µg (N=11) n (%) E	Total (N=69) n (%) E
Boost up to Day 28 after boost	Any TEAE	9 (75) 30	0 (0) 0	11 (100) 29	4 (36) 10	12 (100) 32	11 (100) 43	47 (68) 144
	Related TEAE	9 (75) 23	0 (0) 0	11 (100) 23	2 (18) 6	12 (100) 27	11 (100) 38	45 (65) 117
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (9) 1	2 (18) 5	0 (0) 0	2 (18) 2	5 (7) 8
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (9) 1	1 (9) 4	0 (0) 0	2 (18) 2	4 (6) 7
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_2.sas (Page 1 of 2)

Table 14.3.1-3.1.2-1: Summary of TEAEs - completers only - BNT162b1

Boost + 28 Days completers set

		Older dose ranging cohorts		
Time interval		10 µg (N=12) n (%) E	Total (N=12) n (%) E	Total (N=81) n (%) E
Boost up to Day 28 after boost	Any TEAE	0 (0) 0	0 (0) 0	47 (58) 144
	Related TEAE	0 (0) 0	0 (0) 0	45 (56) 117
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	5 (6) 8
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	4 (5) 7
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_2.sas (Page 2 of 2)

Table 14.3.1-3.1.2-1: Summary of TEAEs - completers only - BNT162b1

Prime or Boost + 28 Days completers set

		Younger dose ranging cohorts							
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=11) n (%) E	20 µg (N=11) n (%) E	30 µg (N=12) n (%) E	50 µg (N=11) n (%) E	60 µg (N=12) n (%) E	Total (N=81) n (%) E
Prime up to Day 28 after boost or after prime (if no boost)	Any TEAE	11 (92) 63	1 (8) 1	11 (100) 63	6 (55) 17	12 (100) 75	11 (100) 78	12 (100) 45	64 (79) 342
	Related TEAE	11 (92) 49	0 (0) 0	11 (100) 54	5 (45) 11	12 (100) 68	11 (100) 71	12 (100) 43	62 (77) 296
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (9) 1	3 (27) 6	0 (0) 0	2 (18) 2	1 (8) 1	7 (9) 10
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (9) 1	1 (9) 4	0 (0) 0	2 (18) 2	1 (8) 1	5 (6) 8
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_2.sas (Page 1 of 2)

Table 14.3.1-3.1.2-1: Summary of TEAEs - completers only - BNT162b1

Prime or Boost + 28 Days completers set

		Older dose ranging cohorts			
Time interval		10 µg (N=12) n (%) E	20 µg (N=1) n (%) E	Total (N=13) n (%) E	Total (N=94) n (%) E
Prime up to Day 28 after boost or after prime (if no boost)	Any TEAE	3 (25) 3	1 (100) 3	4 (31) 6	68 (72) 348
	Related TEAE	0 (0) 0	0 (0) 0	0 (0) 0	62 (66) 296
	Grade >=3 TEAE	1 (8) 1	1 (100) 1	2 (15) 2	9 (10) 12
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	5 (5) 8
	Any TESAE	0 (0) 0	1 (100) 1	1 (8) 1	1 (1) 1
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_2.sas (Page 2 of 2)

Table 14.3.1-3.1.3-1: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b1

Safety set

		Younger dose ranging cohorts							
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	50 µg (N=12) n (%) E	60 µg (N=12) n (%) E	Total (N=84) n (%) E
Prime up to Day 7 after prime	Any TEAE	1 (8) 2	0 (0) 0	3 (25) 7	3 (25) 4	2 (17) 2	1 (8) 1	6 (50) 8	16 (19) 24
	Related TEAE	1 (8) 1	0 (0) 0	3 (25) 7	3 (25) 4	2 (17) 2	1 (8) 1	6 (50) 8	16 (19) 23
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Prime up to boost or Day 28 after prime (whatever comes first)	Any TEAE	1 (8) 6	0 (0) 0	4 (33) 11	3 (25) 4	4 (33) 5	3 (25) 4	6 (50) 9	21 (25) 39
	Related TEAE	1 (8) 1	0 (0) 0	3 (25) 7	3 (25) 4	3 (25) 3	1 (8) 1	6 (50) 8	17 (20) 24
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 1 of 6)

Table 14.3.1-3.1.3-1: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b1

Safety set

		Younger dose ranging cohorts							
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	50 µg (N=12) n (%) E	60 µg (N=12) n (%) E	Total (N=84) n (%) E
Boost up to Day 7 after boost	Any TEAE	5 (42) 12	0 (0) 0	3 (25) 3	3 (25) 8	1 (8) 1	6 (50) 10	N/A	18 (21) 34
	Related TEAE	4 (33) 9	0 (0) 0	3 (25) 3	2 (17) 5	1 (8) 1	5 (42) 9	N/A	15 (18) 27
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	2 (17) 4	0 (0) 0	0 (0) 0	N/A	2 (2) 4
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	1 (8) 3	0 (0) 0	0 (0) 0	N/A	1 (1) 3
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	N/A	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	N/A	0 (0) 0
Boost up to Day 28 after boost	Any TEAE	6 (50) 15	0 (0) 0	4 (33) 5	3 (25) 8	3 (25) 4	6 (50) 13	N/A	22 (26) 45
	Related TEAE	4 (33) 9	0 (0) 0	3 (25) 3	2 (17) 5	2 (17) 2	5 (42) 9	N/A	16 (19) 28
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	2 (17) 4	0 (0) 0	0 (0) 0	N/A	2 (2) 4
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	1 (8) 3	0 (0) 0	0 (0) 0	N/A	1 (1) 3
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	N/A	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	N/A	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 2 of 6)

Table 14.3.1-3.1.3-1: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b1

Safety set

		Younger dose ranging cohorts							
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	50 µg (N=12) n (%) E	60 µg (N=12) n (%) E	Total (N=84) n (%) E
Prime up to Day 28 after boost or after prime (if no boost)	Any TEAE	6 (50) 21	0 (0) 0	7 (58) 16	5 (42) 12	6 (50) 8	8 (67) 17	6 (50) 9	38 (45) 83
	Related TEAE	4 (33) 10	0 (0) 0	6 (50) 10	4 (33) 9	4 (33) 4	6 (50) 10	6 (50) 8	30 (36) 51
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	2 (17) 4	0 (0) 0	0 (0) 0	0 (0) 0	2 (2) 4
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	1 (8) 3	0 (0) 0	0 (0) 0	0 (0) 0	1 (1) 3
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 3 of 6)

Table 14.3.1-3.1.3-1: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b1

Safety set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=120) n (%) E
Prime up to Day 7 after prime	Any TEAE	0 (0) 0	0 (0) 0	5 (42) 9	5 (14) 9	21 (18) 33
	Related TEAE	0 (0) 0	0 (0) 0	4 (33) 6	4 (11) 6	20 (17) 29
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Prime up to boost or Day 28 after prime (whatever comes first)	Any TEAE	3 (25) 3	2 (17) 4	7 (58) 13	12 (33) 20	33 (28) 59
	Related TEAE	0 (0) 0	0 (0) 0	4 (33) 6	4 (11) 6	21 (18) 30
	Grade >=3 TEAE	1 (8) 1	1 (8) 1	1 (8) 1	3 (8) 3	3 (3) 3
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 4 of 6)

Table 14.3.1-3.1.3-1: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b1

Safety set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=120) n (%) E
Boost up to Day 7 after boost	Any TEAE	0 (0) 0	0 (0) 0	4 (33) 4	4 (11) 4	22 (18) 38
	Related TEAE	0 (0) 0	0 (0) 0	3 (25) 3	3 (8) 3	18 (15) 30
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	3 (3) 5
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	2 (2) 4
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Boost up to Day 28 after boost	Any TEAE	0 (0) 0	0 (0) 0	4 (33) 4	4 (11) 4	26 (22) 49
	Related TEAE	0 (0) 0	0 (0) 0	3 (25) 3	3 (8) 3	19 (16) 31
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	3 (3) 5
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	2 (2) 4
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 5 of 6)

Table 14.3.1-3.1.3-1: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b1

Safety set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=120) n (%) E
Prime up to Day 28 after boost or after prime (if no boost)	Any TEAE	3 (25) 3	2 (17) 4	8 (67) 17	13 (36) 24	51 (43) 107
	Related TEAE	0 (0) 0	0 (0) 0	5 (42) 9	5 (14) 9	35 (29) 60
	Grade >=3 TEAE	1 (8) 1	1 (8) 1	2 (17) 2	4 (11) 4	6 (5) 8
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	2 (2) 4
	Any TESAE	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 6 of 6)

Table 14.3.1-3.1.3-1: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b1

Safety boost set

		Younger dose ranging cohorts						
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=11) n (%) E	20 µg (N=11) n (%) E	30 µg (N=12) n (%) E	50 µg (N=11) n (%) E	Total (N=69) n (%) E
Prime up to Day 7 after prime	Any TEAE	1 (8) 2	0 (0) 0	2 (18) 3	3 (27) 4	2 (17) 2	1 (9) 1	9 (13) 12
	Related TEAE	1 (8) 1	0 (0) 0	2 (18) 3	3 (27) 4	2 (17) 2	1 (9) 1	9 (13) 11
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Prime up to boost or Day 28 after prime (whatever comes first)	Any TEAE	1 (8) 6	0 (0) 0	3 (27) 5	3 (27) 4	4 (33) 5	2 (18) 3	13 (19) 23
	Related TEAE	1 (8) 1	0 (0) 0	2 (18) 3	3 (27) 4	3 (25) 3	1 (9) 1	10 (14) 12
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 1 of 6)

Table 14.3.1-3.1.3-1: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b1

Safety boost set

		Younger dose ranging cohorts						
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=11) n (%) E	20 µg (N=11) n (%) E	30 µg (N=12) n (%) E	50 µg (N=11) n (%) E	Total (N=69) n (%) E
Boost up to Day 7 after boost	Any TEAE	5 (42) 12	0 (0) 0	3 (27) 3	3 (27) 8	1 (8) 1	6 (55) 10	18 (26) 34
	Related TEAE	4 (33) 9	0 (0) 0	3 (27) 3	2 (18) 5	1 (8) 1	5 (45) 9	15 (22) 27
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	2 (18) 4	0 (0) 0	0 (0) 0	2 (3) 4
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	1 (9) 3	0 (0) 0	0 (0) 0	1 (1) 3
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Boost up to Day 28 after boost	Any TEAE	6 (50) 15	0 (0) 0	4 (36) 5	3 (27) 8	3 (25) 4	6 (55) 13	22 (32) 45
	Related TEAE	4 (33) 9	0 (0) 0	3 (27) 3	2 (18) 5	2 (17) 2	5 (45) 9	16 (23) 28
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	2 (18) 4	0 (0) 0	0 (0) 0	2 (3) 4
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	1 (9) 3	0 (0) 0	0 (0) 0	1 (1) 3
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 2 of 6)

Table 14.3.1-3.1.3-1: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b1

Safety boost set

		Younger dose ranging cohorts						
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=11) n (%) E	20 µg (N=11) n (%) E	30 µg (N=12) n (%) E	50 µg (N=11) n (%) E	Total (N=69) n (%) E
Prime up to Day 28 after boost or after prime (if no boost)	Any TEAE	6 (50) 21	0 (0) 0	6 (55) 10	5 (45) 12	6 (50) 8	7 (64) 16	30 (43) 67
	Related TEAE	4 (33) 10	0 (0) 0	5 (45) 6	4 (36) 9	4 (33) 4	6 (55) 10	23 (33) 39
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	2 (18) 4	0 (0) 0	0 (0) 0	2 (3) 4
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	1 (9) 3	0 (0) 0	0 (0) 0	1 (1) 3
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 3 of 6)

Table 14.3.1-3.1.3-1: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b1

Safety boost set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=11) n (%) E	30 µg (N=12) n (%) E	Total (N=35) n (%) E	Total (N=104) n (%) E
Prime up to Day 7 after prime	Any TEAE	0 (0) 0	0 (0) 0	5 (42) 9	5 (14) 9	14 (13) 21
	Related TEAE	0 (0) 0	0 (0) 0	4 (33) 6	4 (11) 6	13 (13) 17
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Prime up to boost or Day 28 after prime (whatever comes first)	Any TEAE	3 (25) 3	1 (9) 1	7 (58) 13	11 (31) 17	24 (23) 40
	Related TEAE	0 (0) 0	0 (0) 0	4 (33) 6	4 (11) 6	14 (13) 18
	Grade >=3 TEAE	1 (8) 1	0 (0) 0	1 (8) 1	2 (6) 2	2 (2) 2
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 4 of 6)

Table 14.3.1-3.1.3-1: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b1

Safety boost set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=11) n (%) E	30 µg (N=12) n (%) E	Total (N=35) n (%) E	Total (N=104) n (%) E
Boost up to Day 7 after boost	Any TEAE	0 (0) 0	0 (0) 0	4 (33) 4	4 (11) 4	22 (21) 38
	Related TEAE	0 (0) 0	0 (0) 0	3 (25) 3	3 (9) 3	18 (17) 30
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	3 (3) 5
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	2 (2) 4
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Boost up to Day 28 after boost	Any TEAE	0 (0) 0	0 (0) 0	4 (33) 4	4 (11) 4	26 (25) 49
	Related TEAE	0 (0) 0	0 (0) 0	3 (25) 3	3 (9) 3	19 (18) 31
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	3 (3) 5
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	2 (2) 4
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 5 of 6)

Table 14.3.1-3.1.3-1: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b1

Safety boost set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=11) n (%) E	30 µg (N=12) n (%) E	Total (N=35) n (%) E	Total (N=104) n (%) E
Prime up to Day 28 after boost or after prime (if no boost)	Any TEAE	3 (25) 3	1 (9) 1	8 (67) 17	12 (34) 21	42 (40) 88
	Related TEAE	0 (0) 0	0 (0) 0	5 (42) 9	5 (14) 9	28 (27) 48
	Grade >=3 TEAE	1 (8) 1	0 (0) 0	2 (17) 2	3 (9) 3	5 (5) 7
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	2 (2) 4
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 6 of 6)

Table 14.3.1-3.1.4-1: Summary of TEAEs of special interest - BNT162b1

Safety set

No respective treatment emergent adverse events were recorded.

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.1-3.1.4-1: Summary of TEAEs of special interest - BNT162b1

Safety boost set

No respective treatment emergent adverse events were recorded.

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gastrointestinal disorders	1 (8)	1 (8)	2 (17)	2 (17)	1 (8)	1 (8)	2 (17)	10 (12)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	1 (8)	1 (8)	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	5 (6)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gastrointestinal disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
General disorders and administration site conditions	10 (83)	0 (0)	10 (83)	0 (0)	11 (92)	12 (100)	12 (100)	55 (65)
Chills	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
Fatigue	7 (58)	0 (0)	6 (50)	0 (0)	5 (42)	1 (8)	0 (0)	19 (23)
Influenza like illness	2 (17)	0 (0)	1 (8)	0 (0)	6 (50)	11 (92)	12 (100)	32 (38)
Injection site discolouration	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	3 (4)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 1 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Injection site discomfort	3 (25)	0 (0)	2 (17)	0 (0)	1 (8)	1 (8)	2 (17)	9 (11)
Injection site erythema	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Injection site hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Injection site pain	2 (17)	0 (0)	3 (25)	0 (0)	3 (25)	1 (8)	3 (25)	12 (14)
Injection site reaction	2 (17)	0 (0)	5 (42)	0 (0)	10 (83)	9 (75)	8 (67)	34 (40)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	3 (25)	5 (6)
Infections and infestations	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	1 (8)	4 (5)
Body temperature increased	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 2 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
Musculoskeletal and connective tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	3 (4)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Pain in extremity	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	4 (33)	0 (0)	6 (50)	1 (8)	7 (58)	4 (33)	6 (50)	28 (33)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Head discomfort	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
Headache	4 (33)	0 (0)	5 (42)	0 (0)	7 (58)	4 (33)	3 (25)	23 (27)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Paraesthesia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 3 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	2 (17)	1 (8)	0 (0)	1 (8)	2 (17)	6 (7)
Cough	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	3 (4)
Dysphonia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	3 (4)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Alopecia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pruritus	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 4 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gastrointestinal disorders	1 (8)	1 (8)	2 (17)	2 (17)	1 (8)	1 (8)	2 (17)	10 (12)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	1 (8)	1 (8)	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	5 (6)
Dyspepsia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gastrointestinal disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
General disorders and administration site conditions	11 (92)	0 (0)	10 (83)	0 (0)	11 (92)	12 (100)	12 (100)	56 (67)
Chills	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	3 (4)
Fatigue	7 (58)	0 (0)	6 (50)	0 (0)	5 (42)	1 (8)	0 (0)	19 (23)
Influenza like illness	3 (25)	0 (0)	1 (8)	0 (0)	6 (50)	11 (92)	12 (100)	33 (39)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 5 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Injection site discolouration	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	3 (4)
Injection site discomfort	3 (25)	0 (0)	2 (17)	0 (0)	1 (8)	1 (8)	2 (17)	9 (11)
Injection site erythema	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Injection site hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Injection site pain	3 (25)	0 (0)	3 (25)	0 (0)	3 (25)	1 (8)	4 (33)	14 (17)
Injection site paraesthesia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	3 (25)	0 (0)	5 (42)	0 (0)	10 (83)	9 (75)	8 (67)	35 (42)
Malaise	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pyrexia	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	3 (25)	6 (7)
Infections and infestations	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	3 (4)
Genital herpes	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingivitis	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 6 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Thermal burn	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Investigations	1 (8)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	1 (8)	5 (6)
Body temperature increased	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Muscle strength abnormal	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	3 (4)
Decreased appetite	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	3 (4)
Musculoskeletal and connective tissue disorders	1 (8)	0 (0)	2 (17)	0 (0)	2 (17)	2 (17)	0 (0)	7 (8)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Muscle tightness	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 7 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Musculoskeletal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Myalgia	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Myosclerosis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Pain in extremity	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	4 (33)	0 (0)	6 (50)	1 (8)	7 (58)	5 (42)	6 (50)	29 (35)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Head discomfort	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
Headache	4 (33)	0 (0)	5 (42)	1 (8)	7 (58)	4 (33)	3 (25)	24 (29)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Migraine	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Paraesthesia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Syncope	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 8 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	2 (17)	1 (8)	0 (0)	1 (8)	2 (17)	6 (7)
Cough	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
Dysphonia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	3 (4)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Alopecia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pruritus	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Surgical and medical procedures	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 9 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Papilloma excision	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 10 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Eye disorders	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	2 (2)
Asthenopia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Eye irritation	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Gastrointestinal disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	N/A	3 (4)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Dry mouth	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 11 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
General disorders and administration site conditions	7 (58)	0 (0)	11 (92)	0 (0)	11 (92)	11 (92)	N/A	40 (48)
Fatigue	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Influenza like illness	5 (42)	0 (0)	7 (58)	0 (0)	10 (83)	10 (83)	N/A	32 (38)
Injection site discomfort	1 (8)	0 (0)	3 (25)	0 (0)	3 (25)	0 (0)	N/A	7 (8)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Injection site pain	3 (25)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	N/A	5 (6)
Injection site reaction	4 (33)	0 (0)	6 (50)	0 (0)	8 (67)	11 (92)	N/A	29 (35)
Infections and infestations	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	N/A	3 (4)
Conjunctivitis	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Investigations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 12 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Lymphocyte count increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Metabolism and nutrition disorders	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	N/A	4 (5)
Decreased appetite	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	N/A	4 (5)
Musculoskeletal and connective tissue disorders	1 (8)	0 (0)	1 (8)	1 (8)	1 (8)	2 (17)	N/A	6 (7)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	N/A	1 (1)
Muscle tightness	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Myalgia	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	N/A	2 (2)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Nervous system disorders	4 (33)	0 (0)	5 (42)	1 (8)	3 (25)	3 (25)	N/A	16 (19)
Dizziness	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	N/A	3 (4)
Headache	3 (25)	0 (0)	4 (33)	0 (0)	3 (25)	1 (8)	N/A	11 (13)
Presyncope	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	N/A	2 (2)
Taste disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 13 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	N/A	2 (2)
Depression	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Bladder dysfunction	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	N/A	2 (2)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 14 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Cardiac disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	2 (2)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Tachycardia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Eye disorders	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	2 (2)
Asthenopia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Eye irritation	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Gastrointestinal disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	4 (33)	N/A	5 (6)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 15 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Dry mouth	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Dysphagia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
General disorders and administration site conditions	7 (58)	0 (0)	11 (92)	0 (0)	11 (92)	11 (92)	N/A	40 (48)
Fatigue	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Influenza like illness	5 (42)	0 (0)	7 (58)	0 (0)	10 (83)	10 (83)	N/A	32 (38)
Injection site discomfort	1 (8)	0 (0)	3 (25)	0 (0)	3 (25)	0 (0)	N/A	7 (8)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Injection site pain	3 (25)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	N/A	5 (6)
Injection site reaction	4 (33)	0 (0)	6 (50)	0 (0)	8 (67)	11 (92)	N/A	29 (35)
Immune system disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Seasonal allergy	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (17)	N/A	4 (5)
Conjunctivitis	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 16 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Fungal infection	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	N/A	1 (1)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Investigations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Lymphocyte count increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Metabolism and nutrition disorders	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	N/A	4 (5)
Decreased appetite	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	N/A	4 (5)
Musculoskeletal and connective tissue disorders	1 (8)	0 (0)	1 (8)	1 (8)	2 (17)	2 (17)	N/A	7 (8)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	N/A	2 (2)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	N/A	1 (1)
Muscle tightness	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 17 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Myalgia	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	N/A	2 (2)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Nervous system disorders	5 (42)	0 (0)	7 (58)	2 (17)	4 (33)	3 (25)	N/A	21 (25)
Cervicobrachial syndrome	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Dizziness	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (17)	N/A	4 (5)
Headache	4 (33)	0 (0)	6 (50)	1 (8)	4 (33)	1 (8)	N/A	16 (19)
Presyncope	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	N/A	2 (2)
Taste disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	N/A	2 (2)
Depression	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Bladder dysfunction	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 18 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	1 (8)	N/A	3 (4)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Rhinitis allergic	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	N/A	1 (1)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	N/A	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 19 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Tachycardia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	2 (2)
Asthenopia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	1 (8)	1 (8)	2 (17)	2 (17)	1 (8)	4 (33)	2 (17)	13 (15)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 20 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	1 (8)	1 (8)	2 (17)	0 (0)	1 (8)	1 (8)	0 (0)	6 (7)
Dry mouth	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspepsia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dysphagia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gastrointestinal disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
General disorders and administration site conditions	11 (92)	0 (0)	12 (100)	0 (0)	11 (92)	12 (100)	12 (100)	58 (69)
Chills	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	3 (4)
Fatigue	8 (67)	0 (0)	6 (50)	0 (0)	5 (42)	1 (8)	0 (0)	20 (24)
Influenza like illness	5 (42)	0 (0)	8 (67)	0 (0)	10 (83)	11 (92)	12 (100)	46 (55)
Injection site discolouration	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	3 (4)
Injection site discomfort	3 (25)	0 (0)	5 (42)	0 (0)	3 (25)	1 (8)	2 (17)	14 (17)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 21 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Injection site erythema	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Injection site hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Injection site pain	4 (33)	0 (0)	4 (33)	0 (0)	3 (25)	1 (8)	4 (33)	16 (19)
Injection site paraesthesia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	4 (33)	0 (0)	8 (67)	0 (0)	10 (83)	12 (100)	8 (67)	42 (50)
Malaise	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pyrexia	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	3 (25)	6 (7)
Immune system disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Seasonal allergy	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	2 (17)	1 (8)	1 (8)	2 (17)	1 (8)	7 (8)
Conjunctivitis	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Fungal infection	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 22 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Gingivitis	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Thermal burn	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Investigations	2 (17)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	1 (8)	6 (7)
Body temperature increased	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Lymphocyte count increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle strength abnormal	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	3 (25)	0 (0)	6 (7)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 23 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Decreased appetite	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	3 (25)	0 (0)	6 (7)
Musculoskeletal and connective tissue disorders	1 (8)	0 (0)	3 (25)	1 (8)	3 (25)	3 (25)	0 (0)	11 (13)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Muscle tightness	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (2)
Musculoskeletal chest pain	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	2 (2)
Musculoskeletal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Myalgia	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	1 (8)	0 (0)	4 (5)
Myosclerosis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Pain in extremity	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
Nervous system disorders	6 (50)	0 (0)	8 (67)	2 (17)	8 (67)	6 (50)	6 (50)	36 (43)
Cervicobrachial syndrome	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	2 (17)	0 (0)	5 (6)
Head discomfort	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Headache	5 (42)	0 (0)	8 (67)	1 (8)	8 (67)	5 (42)	3 (25)	30 (36)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Migraine	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Paraesthesia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	3 (4)
Syncope	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Taste disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	1 (8)	3 (4)
Depression	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (2)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bladder dysfunction	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 25 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	3 (25)	2 (17)	0 (0)	2 (17)	2 (17)	9 (11)
Cough	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
Dysphonia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	4 (5)
Rhinitis allergic	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (2)
Alopecia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Pruritus	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Surgical and medical procedures	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Papilloma excision	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 26 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Vascular disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
Hot flush	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 27 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	1 (8)	1 (3)	11 (9)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	55 (46)
Chills	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	19 (16)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	32 (27)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Injection site discomfort	0 (0)	0 (0)	0 (0)	0 (0)	9 (8)
Injection site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	12 (10)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	34 (28)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Body temperature increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	1 (8)	1 (3)	29 (24)
Dizziness	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Head discomfort	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	23 (19)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	2 (17)	2 (6)	3 (3)
Sleep disorder	0 (0)	0 (0)	2 (17)	2 (6)	3 (3)
Renal and urinary disorders	0 (0)	0 (0)	3 (25)	3 (8)	3 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Pollakiuria	0 (0)	0 (0)	3 (25)	3 (8)	3 (3)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	2 (17)	2 (6)	8 (7)
Cough	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Dysphonia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	2 (17)	2 (6)	5 (4)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Alopecia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pruritus	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 31 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Ear pain	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Gastrointestinal disorders	0 (0)	0 (0)	2 (17)	2 (6)	12 (10)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
Dyspepsia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	56 (47)
Chills	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	19 (16)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	33 (28)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 32 of 54)

Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site discomfort	0 (0)	0 (0)	0 (0)	0 (0)	9 (8)
Injection site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	14 (12)
Injection site paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	35 (29)
Malaise	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
Infections and infestations	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)
Genital herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingivitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Thermal burn	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
Body temperature increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle strength abnormal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Musculoskeletal and connective tissue disorders	0 (0)	1 (8)	0 (0)	1 (3)	8 (7)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle tightness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Musculoskeletal pain	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Myosclerosis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	1 (8)	1 (8)	1 (8)	3 (8)	32 (27)
Dizziness	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Head discomfort	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	24 (20)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Migraine	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Syncope	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Psychiatric disorders	0 (0)	0 (0)	2 (17)	2 (6)	3 (3)
Sleep disorder	0 (0)	0 (0)	2 (17)	2 (6)	3 (3)
Renal and urinary disorders	0 (0)	0 (0)	3 (25)	3 (8)	3 (3)
Pollakiuria	0 (0)	0 (0)	3 (25)	3 (8)	3 (3)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Respiratory, thoracic and mediastinal disorders	2 (17)	0 (0)	2 (17)	4 (11)	10 (8)
Cough	2 (17)	0 (0)	0 (0)	2 (6)	6 (5)
Dysphonia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	2 (17)	2 (6)	5 (4)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Alopecia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pruritus	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Surgical and medical procedures	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Papilloma excision	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Asthenopia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Dry mouth	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	40 (33)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	32 (27)
Injection site discomfort	0 (0)	0 (0)	0 (0)	0 (0)	7 (6)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	29 (24)
Infections and infestations	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)
Conjunctivitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Lymphocyte count increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle tightness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	16 (13)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	11 (9)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Taste disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Depression	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Bladder dysfunction	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tachycardia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Asthenopia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	1 (8)	1 (3)	6 (5)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dry mouth	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysphagia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	40 (33)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	32 (27)
Injection site discomfort	0 (0)	0 (0)	0 (0)	0 (0)	7 (6)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	29 (24)
Immune system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Seasonal allergy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	1 (8)	1 (3)	5 (4)
Conjunctivitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Fungal infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	7 (6)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle tightness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	21 (18)
Cervicobrachial syndrome	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	16 (13)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Taste disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Depression	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Bladder dysfunction	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis allergic	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tachycardia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Ear pain	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Asthenopia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	2 (17)	2 (6)	15 (13)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
Dry mouth	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspepsia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Dysphagia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	58 (48)
Chills	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	20 (17)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	46 (38)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site discomfort	0 (0)	0 (0)	0 (0)	0 (0)	14 (12)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Injection site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	16 (13)
Injection site paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	42 (35)
Malaise	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
Immune system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Seasonal allergy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	2 (17)	2 (6)	9 (8)
Conjunctivitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fungal infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Gingivitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Injury, poisoning and procedural complications	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Thermal burn	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
Body temperature increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle strength abnormal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
Musculoskeletal and connective tissue disorders	0 (0)	1 (8)	0 (0)	1 (3)	12 (10)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle tightness	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Musculoskeletal chest pain	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
Musculoskeletal pain	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Myosclerosis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Nervous system disorders	1 (8)	1 (8)	1 (8)	3 (8)	39 (33)
Cervicobrachial syndrome	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	1 (8)	1 (3)	6 (5)
Head discomfort	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	30 (25)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Migraine	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Syncope	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Taste disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	2 (17)	2 (6)	5 (4)
Depression	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	2 (17)	2 (6)	4 (3)
Renal and urinary disorders	0 (0)	0 (0)	3 (25)	3 (8)	3 (3)
Bladder dysfunction	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pollakiuria	0 (0)	0 (0)	3 (25)	3 (8)	3 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Respiratory, thoracic and mediastinal disorders	2 (17)	0 (0)	2 (17)	4 (11)	13 (11)
Cough	2 (17)	0 (0)	0 (0)	2 (6)	6 (5)
Dysphonia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	2 (17)	2 (6)	6 (5)
Rhinitis allergic	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Alopecia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pruritus	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Surgical and medical procedures	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Papilloma excision	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-1: Frequency of subjects with TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gastrointestinal disorders	1 (8)	0 (0)	2 (17)	2 (17)	1 (8)	1 (8)	2 (17)	9 (11)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Diarrhoea	1 (8)	0 (0)	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	4 (5)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gastrointestinal disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
General disorders and administration site conditions	10 (83)	0 (0)	10 (83)	0 (0)	11 (92)	12 (100)	12 (100)	55 (65)
Chills	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
Fatigue	7 (58)	0 (0)	6 (50)	0 (0)	5 (42)	1 (8)	0 (0)	19 (23)
Influenza like illness	2 (17)	0 (0)	1 (8)	0 (0)	6 (50)	11 (92)	12 (100)	32 (38)
Injection site discolouration	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	3 (4)
Injection site discomfort	3 (25)	0 (0)	2 (17)	0 (0)	1 (8)	1 (8)	2 (17)	9 (11)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 1 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Injection site erythema	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Injection site hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Injection site pain	2 (17)	0 (0)	3 (25)	0 (0)	3 (25)	1 (8)	3 (25)	12 (14)
Injection site reaction	2 (17)	0 (0)	5 (42)	0 (0)	10 (83)	9 (75)	8 (67)	34 (40)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	3 (25)	5 (6)
Infections and infestations	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	1 (8)	4 (5)
Body temperature increased	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 2 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Nervous system disorders	4 (33)	0 (0)	6 (50)	1 (8)	7 (58)	4 (33)	6 (50)	28 (33)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Head discomfort	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
Headache	4 (33)	0 (0)	5 (42)	0 (0)	7 (58)	4 (33)	3 (25)	23 (27)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Paraesthesia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	2 (17)	1 (8)	0 (0)	1 (8)	2 (17)	6 (7)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 3 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Cough	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	3 (4)
Dysphonia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	3 (4)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Alopecia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pruritus	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 4 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gastrointestinal disorders	1 (8)	0 (0)	2 (17)	2 (17)	1 (8)	1 (8)	2 (17)	9 (11)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Diarrhoea	1 (8)	0 (0)	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	4 (5)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gastrointestinal disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
General disorders and administration site conditions	11 (92)	0 (0)	10 (83)	0 (0)	11 (92)	12 (100)	12 (100)	56 (67)
Chills	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
Fatigue	7 (58)	0 (0)	6 (50)	0 (0)	5 (42)	1 (8)	0 (0)	19 (23)
Influenza like illness	3 (25)	0 (0)	1 (8)	0 (0)	6 (50)	11 (92)	12 (100)	33 (39)
Injection site discolouration	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	3 (4)
Injection site discomfort	3 (25)	0 (0)	2 (17)	0 (0)	1 (8)	1 (8)	2 (17)	9 (11)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 5 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Injection site erythema	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Injection site hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Injection site pain	3 (25)	0 (0)	3 (25)	0 (0)	3 (25)	1 (8)	4 (33)	14 (17)
Injection site reaction	3 (25)	0 (0)	5 (42)	0 (0)	10 (83)	9 (75)	8 (67)	35 (42)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	3 (25)	5 (6)
Infections and infestations	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	1 (8)	4 (5)
Body temperature increased	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Metabolism and nutrition disorders	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	3 (4)
Decreased appetite	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	3 (4)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 6 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	0 (0)	3 (4)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Nervous system disorders	4 (33)	0 (0)	6 (50)	1 (8)	7 (58)	4 (33)	6 (50)	28 (33)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Head discomfort	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
Headache	4 (33)	0 (0)	5 (42)	0 (0)	7 (58)	4 (33)	3 (25)	23 (27)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Paraesthesia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 7 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	2 (17)	1 (8)	0 (0)	1 (8)	2 (17)	6 (7)
Cough	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	3 (4)
Dysphonia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	3 (4)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Alopecia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pruritus	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 8 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Eye disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Gastrointestinal disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	N/A	3 (4)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Dry mouth	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
General disorders and administration site conditions	7 (58)	0 (0)	11 (92)	0 (0)	11 (92)	11 (92)	N/A	40 (48)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 9 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Fatigue	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Influenza like illness	5 (42)	0 (0)	7 (58)	0 (0)	10 (83)	10 (83)	N/A	32 (38)
Injection site discomfort	1 (8)	0 (0)	3 (25)	0 (0)	3 (25)	0 (0)	N/A	7 (8)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Injection site pain	3 (25)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	N/A	5 (6)
Injection site reaction	4 (33)	0 (0)	6 (50)	0 (0)	8 (67)	11 (92)	N/A	29 (35)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Investigations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Lymphocyte count increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Metabolism and nutrition disorders	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	N/A	4 (5)
Decreased appetite	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	N/A	4 (5)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	2 (17)	N/A	5 (6)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 10 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	N/A	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Myalgia	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	N/A	2 (2)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Nervous system disorders	4 (33)	0 (0)	5 (42)	1 (8)	3 (25)	3 (25)	N/A	16 (19)
Dizziness	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	N/A	3 (4)
Headache	3 (25)	0 (0)	4 (33)	0 (0)	3 (25)	1 (8)	N/A	11 (13)
Presyncope	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	N/A	2 (2)
Taste disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Bladder dysfunction	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	N/A	2 (2)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 11 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 12 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Eye disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Gastrointestinal disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	N/A	3 (4)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Dry mouth	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
General disorders and administration site conditions	7 (58)	0 (0)	11 (92)	0 (0)	11 (92)	11 (92)	N/A	40 (48)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 13 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Fatigue	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Influenza like illness	5 (42)	0 (0)	7 (58)	0 (0)	10 (83)	10 (83)	N/A	32 (38)
Injection site discomfort	1 (8)	0 (0)	3 (25)	0 (0)	3 (25)	0 (0)	N/A	7 (8)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Injection site pain	3 (25)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	N/A	5 (6)
Injection site reaction	4 (33)	0 (0)	6 (50)	0 (0)	8 (67)	11 (92)	N/A	29 (35)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Investigations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Lymphocyte count increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Metabolism and nutrition disorders	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	N/A	4 (5)
Decreased appetite	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	N/A	4 (5)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	2 (17)	N/A	5 (6)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 14 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	N/A	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Myalgia	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	N/A	2 (2)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Nervous system disorders	4 (33)	0 (0)	5 (42)	1 (8)	3 (25)	3 (25)	N/A	16 (19)
Dizziness	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	N/A	3 (4)
Headache	3 (25)	0 (0)	4 (33)	0 (0)	3 (25)	1 (8)	N/A	11 (13)
Presyncope	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	N/A	2 (2)
Taste disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Bladder dysfunction	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	N/A	2 (2)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	N/A	1 (1)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	N/A	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 16 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	1 (8)	0 (0)	2 (17)	2 (17)	1 (8)	2 (17)	2 (17)	10 (12)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	1 (8)	0 (0)	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	4 (5)
Dry mouth	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gastrointestinal disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
General disorders and administration site conditions	11 (92)	0 (0)	12 (100)	0 (0)	11 (92)	12 (100)	12 (100)	58 (69)
Chills	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
Fatigue	8 (67)	0 (0)	6 (50)	0 (0)	5 (42)	1 (8)	0 (0)	20 (24)
Influenza like illness	5 (42)	0 (0)	8 (67)	0 (0)	10 (83)	11 (92)	12 (100)	46 (55)
Injection site discolouration	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	3 (4)
Injection site discomfort	3 (25)	0 (0)	5 (42)	0 (0)	3 (25)	1 (8)	2 (17)	14 (17)
Injection site erythema	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Injection site hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Injection site pain	4 (33)	0 (0)	4 (33)	0 (0)	3 (25)	1 (8)	4 (33)	16 (19)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 18 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Injection site reaction	4 (33)	0 (0)	8 (67)	0 (0)	10 (83)	12 (100)	8 (67)	42 (50)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	3 (25)	5 (6)
Infections and infestations	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
Genital herpes	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Investigations	1 (8)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	1 (8)	5 (6)
Body temperature increased	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Lymphocyte count increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	3 (25)	0 (0)	6 (7)
Decreased appetite	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	3 (25)	0 (0)	6 (7)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	3 (25)	0 (0)	6 (7)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 19 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Myalgia	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Nervous system disorders	5 (42)	0 (0)	8 (67)	2 (17)	8 (67)	6 (50)	6 (50)	35 (42)
Dizziness	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (17)	0 (0)	4 (5)
Head discomfort	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
Headache	4 (33)	0 (0)	8 (67)	0 (0)	8 (67)	5 (42)	3 (25)	28 (33)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Paraesthesia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	3 (4)
Taste disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (2)
Hallucination	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 20 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Sleep disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bladder dysfunction	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	2 (17)	2 (17)	0 (0)	2 (17)	2 (17)	8 (10)
Cough	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	3 (4)
Dysphonia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	4 (5)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (2)
Alopecia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Pruritus	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 21 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Hot flush	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 22 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	9 (8)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	55 (46)
Chills	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	19 (16)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	32 (27)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site discomfort	0 (0)	0 (0)	0 (0)	0 (0)	9 (8)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 23 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Injection site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	12 (10)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	34 (28)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Body temperature increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 24 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	28 (23)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Head discomfort	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	23 (19)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Sleep disorder	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Renal and urinary disorders	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Pollakiuria	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	2 (17)	2 (6)	8 (7)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 25 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Cough	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Dysphonia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	2 (17)	2 (6)	5 (4)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Alopecia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pruritus	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 26 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	9 (8)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	56 (47)
Chills	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	19 (16)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	33 (28)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site discomfort	0 (0)	0 (0)	0 (0)	0 (0)	9 (8)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 27 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Injection site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	14 (12)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	35 (29)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Body temperature increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 28 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	28 (23)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Head discomfort	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	23 (19)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Sleep disorder	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Renal and urinary disorders	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Pollakiuria	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 29 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	2 (17)	2 (6)	8 (7)
Cough	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Dysphonia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	2 (17)	2 (6)	5 (4)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Alopecia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pruritus	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 30 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Dry mouth	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	40 (33)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 31 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	32 (27)
Injection site discomfort	0 (0)	0 (0)	0 (0)	0 (0)	7 (6)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	29 (24)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	16 (13)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	11 (9)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Taste disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Bladder dysfunction	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 34 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Dry mouth	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	40 (33)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 35 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	32 (27)
Injection site discomfort	0 (0)	0 (0)	0 (0)	0 (0)	7 (6)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	29 (24)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 36 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	16 (13)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	11 (9)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Taste disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Bladder dysfunction	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 37 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 38 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	1 (8)	1 (3)	11 (9)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Dry mouth	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 39 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	58 (48)
Chills	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	20 (17)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	46 (38)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site discomfort	0 (0)	0 (0)	0 (0)	0 (0)	14 (12)
Injection site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	16 (13)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	42 (35)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Genital herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
Body temperature increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 41 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	35 (29)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Head discomfort	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	28 (23)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Taste disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 42 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Sleep disorder	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Renal and urinary disorders	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Bladder dysfunction	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pollakiuria	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	2 (17)	2 (6)	10 (8)
Cough	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Dysphonia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	2 (17)	2 (6)	6 (5)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Alopecia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pruritus	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 43 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 44 of 44)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 7 after prime

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Gastrointestinal disorders	1 (8)	0 (0)	1 (9)	2 (18)	1 (8)	1 (9)	6 (9)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Diarrhoea	1 (8)	0 (0)	1 (9)	0 (0)	1 (8)	0 (0)	3 (4)
Gastrointestinal disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
General disorders and administration site conditions	10 (83)	0 (0)	9 (82)	0 (0)	11 (92)	11 (100)	41 (59)
Chills	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	7 (58)	0 (0)	5 (45)	0 (0)	5 (42)	1 (9)	18 (26)
Influenza like illness	2 (17)	0 (0)	0 (0)	0 (0)	6 (50)	10 (91)	18 (26)
Injection site discolouration	0 (0)	0 (0)	1 (9)	0 (0)	2 (17)	0 (0)	3 (4)
Injection site discomfort	3 (25)	0 (0)	2 (18)	0 (0)	1 (8)	1 (9)	7 (10)
Injection site erythema	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 1 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 7 after prime

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Injection site pain	2 (17)	0 (0)	3 (27)	0 (0)	3 (25)	1 (9)	9 (13)
Injection site reaction	2 (17)	0 (0)	4 (36)	0 (0)	10 (83)	8 (73)	24 (35)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	2 (3)
Infections and infestations	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	1 (9)	0 (0)	1 (8)	1 (9)	3 (4)
Body temperature increased	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	2 (3)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	2 (3)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	2 (3)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	2 (3)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nervous system disorders	4 (33)	0 (0)	6 (55)	1 (9)	7 (58)	3 (27)	21 (30)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 2 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 7 after prime

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Head discomfort	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	4 (33)	0 (0)	5 (45)	0 (0)	7 (58)	3 (27)	19 (28)
Paraesthesia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Sleep disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	1 (9)	3 (4)
Cough	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	2 (3)
Dysphonia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	0 (0)	2 (3)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Alopecia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pruritus	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 3 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 7 after prime

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Hot flush	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 4 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Gastrointestinal disorders	1 (8)	0 (0)	1 (9)	2 (18)	1 (8)	1 (9)	6 (9)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Diarrhoea	1 (8)	0 (0)	1 (9)	0 (0)	1 (8)	0 (0)	3 (4)
Gastrointestinal disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
General disorders and administration site conditions	11 (92)	0 (0)	9 (82)	0 (0)	11 (92)	11 (100)	42 (61)
Chills	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	7 (58)	0 (0)	5 (45)	0 (0)	5 (42)	1 (9)	18 (26)
Influenza like illness	3 (25)	0 (0)	0 (0)	0 (0)	6 (50)	10 (91)	19 (28)
Injection site discolouration	0 (0)	0 (0)	1 (9)	0 (0)	2 (17)	0 (0)	3 (4)
Injection site discomfort	3 (25)	0 (0)	2 (18)	0 (0)	1 (8)	1 (9)	7 (10)
Injection site erythema	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 5 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Injection site pain	3 (25)	0 (0)	3 (27)	0 (0)	3 (25)	1 (9)	10 (14)
Injection site reaction	3 (25)	0 (0)	4 (36)	0 (0)	10 (83)	8 (73)	25 (36)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	2 (3)
Infections and infestations	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	1 (9)	0 (0)	1 (8)	1 (9)	3 (4)
Body temperature increased	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	2 (3)
Metabolism and nutrition disorders	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	3 (4)
Decreased appetite	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	3 (4)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	2 (18)	3 (4)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nervous system disorders	4 (33)	0 (0)	6 (55)	1 (9)	7 (58)	3 (27)	21 (30)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 6 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Head discomfort	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	4 (33)	0 (0)	5 (45)	0 (0)	7 (58)	3 (27)	19 (28)
Paraesthesia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Sleep disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	1 (9)	3 (4)
Cough	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	2 (3)
Dysphonia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	0 (0)	2 (3)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Alopecia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pruritus	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 7 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Vascular disorders	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 8 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	3 (4)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dry mouth	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
General disorders and administration site conditions	7 (58)	0 (0)	11 (100)	0 (0)	11 (92)	11 (100)	40 (58)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 9 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Fatigue	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	5 (42)	0 (0)	7 (64)	0 (0)	10 (83)	10 (91)	32 (46)
Injection site discomfort	1 (8)	0 (0)	3 (27)	0 (0)	3 (25)	0 (0)	7 (10)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Injection site pain	3 (25)	0 (0)	1 (9)	0 (0)	1 (8)	0 (0)	5 (7)
Injection site reaction	4 (33)	0 (0)	6 (55)	0 (0)	8 (67)	11 (100)	29 (42)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Investigations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	4 (6)
Decreased appetite	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	4 (6)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	1 (9)	1 (9)	1 (8)	2 (18)	5 (7)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 10 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Myalgia	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	2 (3)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nervous system disorders	4 (33)	0 (0)	5 (45)	1 (9)	3 (25)	3 (27)	16 (23)
Dizziness	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	2 (18)	3 (4)
Headache	3 (25)	0 (0)	4 (36)	0 (0)	3 (25)	1 (9)	11 (16)
Presyncope	1 (8)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	2 (3)
Taste disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bladder dysfunction	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (9)	2 (3)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 11 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 12 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	3 (4)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dry mouth	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
General disorders and administration site conditions	7 (58)	0 (0)	11 (100)	0 (0)	11 (92)	11 (100)	40 (58)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Fatigue	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	5 (42)	0 (0)	7 (64)	0 (0)	10 (83)	10 (91)	32 (46)
Injection site discomfort	1 (8)	0 (0)	3 (27)	0 (0)	3 (25)	0 (0)	7 (10)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Injection site pain	3 (25)	0 (0)	1 (9)	0 (0)	1 (8)	0 (0)	5 (7)
Injection site reaction	4 (33)	0 (0)	6 (55)	0 (0)	8 (67)	11 (100)	29 (42)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Investigations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	4 (6)
Decreased appetite	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	4 (6)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	1 (9)	1 (9)	1 (8)	2 (18)	5 (7)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 14 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Myalgia	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	2 (3)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nervous system disorders	4 (33)	0 (0)	5 (45)	1 (9)	3 (25)	3 (27)	16 (23)
Dizziness	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	2 (18)	3 (4)
Headache	3 (25)	0 (0)	4 (36)	0 (0)	3 (25)	1 (9)	11 (16)
Presyncope	1 (8)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	2 (3)
Taste disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bladder dysfunction	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (9)	2 (3)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 15 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 16 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	1 (8)	0 (0)	1 (9)	2 (18)	1 (8)	2 (18)	7 (10)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	1 (8)	0 (0)	1 (9)	0 (0)	1 (8)	0 (0)	3 (4)
Dry mouth	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 17 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Gastrointestinal disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
General disorders and administration site conditions	11 (92)	0 (0)	11 (100)	0 (0)	11 (92)	11 (100)	44 (64)
Chills	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	8 (67)	0 (0)	5 (45)	0 (0)	5 (42)	1 (9)	19 (28)
Influenza like illness	5 (42)	0 (0)	7 (64)	0 (0)	10 (83)	10 (91)	32 (46)
Injection site discolouration	0 (0)	0 (0)	1 (9)	0 (0)	2 (17)	0 (0)	3 (4)
Injection site discomfort	3 (25)	0 (0)	5 (45)	0 (0)	3 (25)	1 (9)	12 (17)
Injection site erythema	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	2 (3)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Injection site pain	4 (33)	0 (0)	4 (36)	0 (0)	3 (25)	1 (9)	12 (17)
Injection site reaction	4 (33)	0 (0)	7 (64)	0 (0)	10 (83)	11 (100)	32 (46)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Infections and infestations	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	2 (3)
Genital herpes	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Investigations	1 (8)	0 (0)	1 (9)	0 (0)	1 (8)	1 (9)	4 (6)
Body temperature increased	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	2 (3)
Lymphocyte count increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	3 (27)	6 (9)
Decreased appetite	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	3 (27)	6 (9)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	1 (9)	1 (9)	1 (8)	3 (27)	6 (9)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Myalgia	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nervous system disorders	5 (42)	0 (0)	8 (73)	2 (18)	8 (67)	5 (45)	28 (41)
Dizziness	0 (0)	0 (0)	0 (0)	1 (9)	1 (8)	2 (18)	4 (6)
Head discomfort	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	4 (33)	0 (0)	8 (73)	0 (0)	8 (67)	4 (36)	24 (35)
Paraesthesia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Presyncope	1 (8)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	2 (3)
Taste disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bladder dysfunction	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	1 (9)	2 (18)	0 (0)	2 (18)	5 (7)
Cough	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	2 (3)
Dysphonia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	1 (9)	3 (4)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (3)
Alopecia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Pruritus	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	2 (3)
Hot flush	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Gastrointestinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Gastrointestinal disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	41 (39)
Chills	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	18 (17)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	18 (17)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site discomfort	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
Injection site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	9 (9)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	24 (23)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Body temperature increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	21 (20)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Head discomfort	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	19 (18)
Paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Sleep disorder	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Pollakiuria	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	2 (17)	2 (6)	5 (5)
Cough	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Dysphonia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Alopecia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pruritus	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 25 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Gastrointestinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Gastrointestinal disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	42 (40)
Chills	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	18 (17)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	19 (18)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site discomfort	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
Injection site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 26 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	10 (10)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	25 (24)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Body temperature increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	21 (20)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Head discomfort	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	19 (18)
Paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Sleep disorder	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Pollakiuria	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	2 (17)	2 (6)	5 (5)
Cough	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Dysphonia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Alopecia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pruritus	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 28 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 29 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Dry mouth	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	40 (38)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	32 (31)
Injection site discomfort	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	29 (28)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	16 (15)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	11 (11)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Taste disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Bladder dysfunction	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 32 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 33 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Dry mouth	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	40 (38)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	32 (31)
Injection site discomfort	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	29 (28)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	16 (15)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	11 (11)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Taste disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Bladder dysfunction	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 37 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	1 (8)	1 (3)	8 (8)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Dry mouth	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 38 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Gastrointestinal disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	44 (42)
Chills	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	19 (18)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	32 (31)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site discomfort	0 (0)	0 (0)	0 (0)	0 (0)	12 (12)
Injection site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	12 (12)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	32 (31)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 39 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Genital herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Body temperature increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Lymphocyte count increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 40 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	28 (27)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Head discomfort	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	24 (23)
Paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Taste disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Bladder dysfunction	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pollakiuria	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 41 of 42)

Table 14.3.1-3.2.2-1: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	2 (17)	2 (6)	7 (7)
Cough	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Dysphonia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	2 (17)	2 (6)	5 (5)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Alopecia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pruritus	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 42 of 42)

Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 1 of 12)

Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Migraine	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Syncope	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 2 of 12)

Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Eye disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	N/A	3 (4)
Influenza like illness	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	N/A	3 (4)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Dizziness	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	N/A	2 (2)
Depression	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 3 of 12)

Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Eye disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	N/A	3 (4)
Influenza like illness	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	N/A	3 (4)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Dizziness	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	N/A	2 (2)
Depression	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 4 of 12)

Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	1 (8)	4 (5)
Influenza like illness	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	0 (0)	3 (4)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (2)
Dizziness	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Migraine	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Syncope	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 5 of 12)

Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Depression	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 6 of 12)

Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pollakiuria	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 7 of 12)

Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	1 (8)	1 (8)	0 (0)	2 (6)	3 (3)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Migraine	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Syncope	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pollakiuria	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 8 of 12)

Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Depression	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 9 of 12)

Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Depression	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 10 of 12)

Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	1 (8)	1 (8)	0 (0)	2 (6)	4 (3)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Migraine	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Syncope	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Depression	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pollakiuria	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 12 of 12)

Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 7 after prime

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Nervous system disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Headache	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Migraine	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 2 of 12)

Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (18)	3 (4)
Influenza like illness	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (18)	3 (4)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Depression	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (18)	3 (4)
Influenza like illness	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (18)	3 (4)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Depression	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (18)	3 (4)
Influenza like illness	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (18)	3 (4)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Dizziness	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Headache	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Migraine	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Depression	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pollakiuria	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Nervous system disorders	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Migraine	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pollakiuria	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 8 of 12)

Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Depression	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Depression	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Migraine	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Depression	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.3-1: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pollakiuria	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 12 of 12)

Table 14.3.1-3.2.4-1: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 1 of 10)

Table 14.3.1-3.2.4-1: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 2 of 10)

Table 14.3.1-3.2.4-1: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Eye disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	N/A	3 (4)
Influenza like illness	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	N/A	3 (4)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Dizziness	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 3 of 10)

Table 14.3.1-3.2.4-1: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Eye disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	N/A	3 (4)
Influenza like illness	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	N/A	3 (4)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Dizziness	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 4 of 10)

Table 14.3.1-3.2.4-1: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	1 (8)	4 (5)
Influenza like illness	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	0 (0)	3 (4)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 5 of 10)

Table 14.3.1-3.2.4-1: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 6 of 10)

Table 14.3.1-3.2.4-1: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 7 of 10)

Table 14.3.1-3.2.4-1: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 8 of 10)

Table 14.3.1-3.2.4-1: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 9 of 10)

Table 14.3.1-3.2.4-1: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 10 of 10)

Table 14.3.1-3.2.4-1: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (18)	3 (4)
Influenza like illness	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (18)	3 (4)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 1 of 6)

Table 14.3.1-3.2.4-1: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (18)	3 (4)
Influenza like illness	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (18)	3 (4)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 2 of 6)

Table 14.3.1-3.2.4-1: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (18)	3 (4)
Influenza like illness	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (18)	3 (4)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 3 of 6)

Table 14.3.1-3.2.4-1: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 4 of 6)

Table 14.3.1-3.2.4-1: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 5 of 6)

Table 14.3.1-3.2.4-1: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 6 of 6)

Table 14.3.1-3.2.5-1: Frequency of subjects with serious TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Syncope	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_5.sas (Page 1 of 4)

Table 14.3.1-3.2.5-1: Frequency of subjects with serious TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Syncope	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_5.sas (Page 2 of 4)

Table 14.3.1-3.2.5-1: Frequency of subjects with serious TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Nervous system disorders	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Syncope	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_5.sas (Page 3 of 4)

Table 14.3.1-3.2.5-1: Frequency of subjects with serious TEAEs by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Nervous system disorders	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Syncope	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_5.sas (Page 4 of 4)

Table 14.3.1-3.2.5-1: Frequency of subjects with serious TEAEs by SOC and PT - BNT162b1

Safety boost set

No respective treatment emergent adverse events were recorded.

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.1-3.2.6-1: Frequency of subjects with serious TEAEs related to IMP by SOC and PT - BNT162b1

Safety set

No respective treatment emergent adverse events were recorded.

Table 14.3.1-3.2.6-1: Frequency of subjects with serious TEAEs related to IMP by SOC and PT - BNT162b1

Safety boost set

No respective treatment emergent adverse events were recorded.

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.1-3.2.7-1: Frequency of subjects with TEAEs with unresolved, fatal or unknown outcome by SOC and PT - BNT162b1

Safety set

No respective treatment emergent adverse events were recorded.

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.1-3.2.7-1: Frequency of subjects with TEAEs with unresolved, fatal or unknown outcome by SOC and PT - BNT162b1

Safety boost set

No respective treatment emergent adverse events were recorded.

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime + 7 Days completers set

Prime up to Day 7 after prime

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=83) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gastrointestinal disorders	1 (8)	1 (8)	2 (17)	2 (18)	1 (8)	1 (8)	2 (17)	10 (12)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	1 (8)	1 (8)	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	5 (6)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gastrointestinal disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
General disorders and administration site conditions	10 (83)	0 (0)	10 (83)	0 (0)	11 (92)	12 (100)	12 (100)	55 (66)
Chills	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
Fatigue	7 (58)	0 (0)	6 (50)	0 (0)	5 (42)	1 (8)	0 (0)	19 (23)
Influenza like illness	2 (17)	0 (0)	1 (8)	0 (0)	6 (50)	11 (92)	12 (100)	32 (39)
Injection site discolouration	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	3 (4)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 1 of 8)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime + 7 Days completers set

Prime up to Day 7 after prime

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=83) n (%)
Injection site discomfort	3 (25)	0 (0)	2 (17)	0 (0)	1 (8)	1 (8)	2 (17)	9 (11)
Injection site erythema	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Injection site hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Injection site pain	2 (17)	0 (0)	3 (25)	0 (0)	3 (25)	1 (8)	3 (25)	12 (14)
Injection site reaction	2 (17)	0 (0)	5 (42)	0 (0)	10 (83)	9 (75)	8 (67)	34 (41)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	3 (25)	5 (6)
Infections and infestations	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	1 (8)	4 (5)
Body temperature increased	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 2 of 8)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime + 7 Days completers set

Prime up to Day 7 after prime

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=83) n (%)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
Musculoskeletal and connective tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	3 (4)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Pain in extremity	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	4 (33)	0 (0)	6 (50)	1 (9)	7 (58)	4 (33)	6 (50)	28 (34)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Head discomfort	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
Headache	4 (33)	0 (0)	5 (42)	0 (0)	7 (58)	4 (33)	3 (25)	23 (28)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Paraesthesia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 3 of 8)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime + 7 Days completers set

Prime up to Day 7 after prime

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=83) n (%)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	2 (17)	1 (9)	0 (0)	1 (8)	2 (17)	6 (7)
Cough	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	3 (4)
Dysphonia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	1 (8)	1 (9)	0 (0)	0 (0)	1 (8)	3 (4)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Alopecia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pruritus	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 4 of 8)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime + 7 Days completers set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=119) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	1 (8)	1 (3)	11 (9)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	55 (46)
Chills	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	19 (16)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	32 (27)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 5 of 8)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime + 7 Days completers set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=119) n (%)
Injection site discomfort	0 (0)	0 (0)	0 (0)	0 (0)	9 (8)
Injection site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	12 (10)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	34 (29)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Body temperature increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 6 of 8)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime + 7 Days completers set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=119) n (%)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	1 (8)	1 (3)	29 (24)
Dizziness	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Head discomfort	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	23 (19)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	2 (17)	2 (6)	3 (3)
Sleep disorder	0 (0)	0 (0)	2 (17)	2 (6)	3 (3)
Renal and urinary disorders	0 (0)	0 (0)	3 (25)	3 (8)	3 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime + 7 Days completers set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=119) n (%)
Pollakiuria	0 (0)	0 (0)	3 (25)	3 (8)	3 (3)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	2 (17)	2 (6)	8 (7)
Cough	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Dysphonia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	2 (17)	2 (6)	5 (4)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Alopecia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pruritus	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 8 of 8)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime to Boost or Prime + 28 Days completers set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	60 µg (N=12) n (%)	Total (N=81) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gastrointestinal disorders	1 (8)	1 (8)	1 (9)	2 (18)	1 (8)	1 (9)	2 (17)	9 (11)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	1 (8)	1 (8)	1 (9)	0 (0)	1 (8)	0 (0)	0 (0)	4 (5)
Dyspepsia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gastrointestinal disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (8)	2 (2)
General disorders and administration site conditions	11 (92)	0 (0)	9 (82)	0 (0)	11 (92)	11 (100)	12 (100)	54 (67)
Chills	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	7 (58)	0 (0)	5 (45)	0 (0)	5 (42)	1 (9)	0 (0)	18 (22)
Influenza like illness	3 (25)	0 (0)	0 (0)	0 (0)	6 (50)	10 (91)	12 (100)	31 (38)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime to Boost or Prime + 28 Days completers set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	60 µg (N=12) n (%)	Total (N=81) n (%)
Injection site discolouration	0 (0)	0 (0)	1 (9)	0 (0)	2 (17)	0 (0)	0 (0)	3 (4)
Injection site discomfort	3 (25)	0 (0)	2 (18)	0 (0)	1 (8)	1 (9)	2 (17)	9 (11)
Injection site erythema	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (1)
Injection site hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Injection site pain	3 (25)	0 (0)	3 (27)	0 (0)	3 (25)	1 (9)	4 (33)	14 (17)
Injection site paraesthesia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	3 (25)	0 (0)	4 (36)	0 (0)	10 (83)	8 (73)	8 (67)	33 (41)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	3 (25)	5 (6)
Infections and infestations	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	0 (0)	1 (8)	3 (4)
Genital herpes	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingivitis	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime to Boost or Prime + 28 Days completers set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	60 µg (N=12) n (%)	Total (N=81) n (%)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Thermal burn	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Investigations	1 (8)	0 (0)	1 (9)	0 (0)	1 (8)	1 (9)	1 (8)	5 (6)
Body temperature increased	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Muscle strength abnormal	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	0 (0)	3 (4)
Decreased appetite	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	0 (0)	3 (4)
Musculoskeletal and connective tissue disorders	1 (8)	0 (0)	1 (9)	0 (0)	2 (17)	2 (18)	0 (0)	6 (7)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (1)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Muscle tightness	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime to Boost or Prime + 28 Days completers set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	60 µg (N=12) n (%)	Total (N=81) n (%)
Myalgia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myosclerosis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (1)
Pain in extremity	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	4 (33)	0 (0)	6 (55)	1 (9)	7 (58)	4 (36)	6 (50)	28 (35)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Head discomfort	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
Headache	4 (33)	0 (0)	5 (45)	1 (9)	7 (58)	3 (27)	3 (25)	23 (28)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Migraine	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Paraesthesia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Syncope	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime to Boost or Prime + 28 Days completers set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	60 µg (N=12) n (%)	Total (N=81) n (%)
Sleep disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (1)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	1 (9)	2 (17)	5 (6)
Cough	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	1 (8)	3 (4)
Dysphonia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	0 (0)	1 (8)	3 (4)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Alopecia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pruritus	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime to Boost or Prime + 28 Days completers set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=117) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Ear pain	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Gastrointestinal disorders	0 (0)	0 (0)	2 (17)	2 (6)	11 (9)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Dyspepsia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	54 (46)
Chills	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	18 (15)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	31 (26)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime to Boost or Prime + 28 Days completers set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=117) n (%)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site discomfort	0 (0)	0 (0)	0 (0)	0 (0)	9 (8)
Injection site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	14 (12)
Injection site paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	33 (28)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
Infections and infestations	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)
Genital herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingivitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime to Boost or Prime + 28 Days completers set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=117) n (%)
Injury, poisoning and procedural complications	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Thermal burn	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
Body temperature increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle strength abnormal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Musculoskeletal and connective tissue disorders	0 (0)	1 (8)	0 (0)	1 (3)	7 (6)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle tightness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
Musculoskeletal pain	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime to Boost or Prime + 28 Days completers set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=117) n (%)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myosclerosis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	1 (8)	1 (8)	1 (8)	3 (8)	31 (26)
Dizziness	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Head discomfort	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	23 (20)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Migraine	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Syncope	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	2 (17)	2 (6)	3 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 9 of 10)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime to Boost or Prime + 28 Days completers set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=117) n (%)
Sleep disorder	0 (0)	0 (0)	2 (17)	2 (6)	3 (3)
Renal and urinary disorders	0 (0)	0 (0)	3 (25)	3 (8)	3 (3)
Pollakiuria	0 (0)	0 (0)	3 (25)	3 (8)	3 (3)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	2 (17)	0 (0)	2 (17)	4 (11)	9 (8)
Cough	2 (17)	0 (0)	0 (0)	2 (6)	5 (4)
Dysphonia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	2 (17)	2 (6)	5 (4)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Alopecia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pruritus	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 10 of 10)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Boost + 7 Days completers set

Boost up to Day 7 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	1 (8)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (3)
Asthenopia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	3 (4)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dry mouth	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 1 of 8)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Boost + 7 Days completers set

Boost up to Day 7 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
General disorders and administration site conditions	7 (58)	0 (0)	11 (100)	0 (0)	11 (92)	11 (100)	40 (58)
Fatigue	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	5 (42)	0 (0)	7 (64)	0 (0)	10 (83)	10 (91)	32 (46)
Injection site discomfort	1 (8)	0 (0)	3 (27)	0 (0)	3 (25)	0 (0)	7 (10)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Injection site pain	3 (25)	0 (0)	1 (9)	0 (0)	1 (8)	0 (0)	5 (7)
Injection site reaction	4 (33)	0 (0)	6 (55)	0 (0)	8 (67)	11 (100)	29 (42)
Infections and infestations	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	2 (18)	3 (4)
Conjunctivitis	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Investigations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 2 of 8)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Boost + 7 Days completers set

Boost up to Day 7 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Lymphocyte count increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	4 (6)
Decreased appetite	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	4 (6)
Musculoskeletal and connective tissue disorders	1 (8)	0 (0)	1 (9)	1 (9)	1 (8)	2 (18)	6 (9)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Muscle tightness	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Myalgia	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	2 (3)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nervous system disorders	4 (33)	0 (0)	5 (45)	1 (9)	3 (25)	3 (27)	16 (23)
Dizziness	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	2 (18)	3 (4)
Headache	3 (25)	0 (0)	4 (36)	0 (0)	3 (25)	1 (9)	11 (16)
Presyncope	1 (8)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	2 (3)
Taste disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 3 of 8)

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Boost + 7 Days completers set

Boost up to Day 7 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Depression	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bladder dysfunction	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (9)	2 (3)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 4 of 8)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Boost + 7 Days completers set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Asthenopia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Dry mouth	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 5 of 8)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Boost + 7 Days completers set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	40 (38)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	32 (31)
Injection site discomfort	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	29 (28)
Infections and infestations	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
Conjunctivitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 6 of 8)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Boost + 7 Days completers set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Lymphocyte count increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle tightness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	16 (15)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	11 (11)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Taste disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 7 of 8)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Boost + 7 Days completers set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Depression	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Bladder dysfunction	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 8 of 8)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Boost + 28 Days completers set

Boost up to Day 28 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Cardiac disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	2 (3)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Tachycardia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Eye disorders	1 (8)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (3)
Asthenopia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	4 (36)	5 (7)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Dry mouth	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 1 of 10)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Boost + 28 Days completers set

Boost up to Day 28 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Dysphagia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
General disorders and administration site conditions	7 (58)	0 (0)	11 (100)	0 (0)	11 (92)	11 (100)	40 (58)
Fatigue	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	5 (42)	0 (0)	7 (64)	0 (0)	10 (83)	10 (91)	32 (46)
Injection site discomfort	1 (8)	0 (0)	3 (27)	0 (0)	3 (25)	0 (0)	7 (10)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Injection site pain	3 (25)	0 (0)	1 (9)	0 (0)	1 (8)	0 (0)	5 (7)
Injection site reaction	4 (33)	0 (0)	6 (55)	0 (0)	8 (67)	11 (100)	29 (42)
Immune system disorders	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Seasonal allergy	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	1 (9)	1 (8)	2 (18)	4 (6)
Conjunctivitis	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Fungal infection	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Boost + 28 Days completers set

Boost up to Day 28 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Investigations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	4 (6)
Decreased appetite	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	4 (6)
Musculoskeletal and connective tissue disorders	1 (8)	0 (0)	1 (9)	1 (9)	2 (17)	2 (18)	7 (10)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	2 (3)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Muscle tightness	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Myalgia	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	2 (3)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nervous system disorders	5 (42)	0 (0)	7 (64)	2 (18)	4 (33)	3 (27)	21 (30)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 3 of 10)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Boost + 28 Days completers set

Boost up to Day 28 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Cervicobrachial syndrome	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	2 (18)	4 (6)
Headache	4 (33)	0 (0)	6 (55)	1 (9)	4 (33)	1 (9)	16 (23)
Presyncope	1 (8)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	2 (3)
Taste disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Depression	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	1 (9)	3 (4)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Rhinitis allergic	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 4 of 10)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Boost + 28 Days completers set

Boost up to Day 28 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 5 of 10)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Boost + 28 Days completers set

Boost up to Day 28 after boost

	Older dose ranging cohorts		
System organ class Preferred term	10 µg (N=12) n (%)	Total (N=12) n (%)	Total (N=81) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	2 (2)
Cardiovascular disorder	0 (0)	0 (0)	1 (1)
Tachycardia	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (1)
Ear pain	0 (0)	0 (0)	1 (1)
Eye disorders	0 (0)	0 (0)	2 (2)
Asthenopia	0 (0)	0 (0)	1 (1)
Eye irritation	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	5 (6)
Abdominal pain	0 (0)	0 (0)	1 (1)
Diarrhoea	0 (0)	0 (0)	1 (1)
Dry mouth	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Boost + 28 Days completers set

Boost up to Day 28 after boost

	Older dose ranging cohorts		
System organ class Preferred term	10 µg (N=12) n (%)	Total (N=12) n (%)	Total (N=81) n (%)
Dysphagia	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	40 (49)
Fatigue	0 (0)	0 (0)	1 (1)
Influenza like illness	0 (0)	0 (0)	32 (40)
Injection site discomfort	0 (0)	0 (0)	7 (9)
Injection site haematoma	0 (0)	0 (0)	1 (1)
Injection site pain	0 (0)	0 (0)	5 (6)
Injection site reaction	0 (0)	0 (0)	29 (36)
Immune system disorders	0 (0)	0 (0)	1 (1)
Seasonal allergy	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	4 (5)
Conjunctivitis	0 (0)	0 (0)	1 (1)
Fungal infection	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Boost + 28 Days completers set

Boost up to Day 28 after boost

	Older dose ranging cohorts		
System organ class Preferred term	10 µg (N=12) n (%)	Total (N=12) n (%)	Total (N=81) n (%)
Oral herpes	0 (0)	0 (0)	1 (1)
Rhinitis	0 (0)	0 (0)	1 (1)
Tinea pedis	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	4 (5)
Decreased appetite	0 (0)	0 (0)	4 (5)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	7 (9)
Arthralgia	0 (0)	0 (0)	2 (2)
Back pain	0 (0)	0 (0)	1 (1)
Muscle tightness	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	1 (1)
Myalgia	0 (0)	0 (0)	2 (2)
Pain in extremity	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	21 (26)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Boost + 28 Days completers set

Boost up to Day 28 after boost

	Older dose ranging cohorts		
System organ class Preferred term	10 µg (N=12) n (%)	Total (N=12) n (%)	Total (N=81) n (%)
Cervicobrachial syndrome	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	4 (5)
Headache	0 (0)	0 (0)	16 (20)
Presyncope	0 (0)	0 (0)	2 (2)
Taste disorder	0 (0)	0 (0)	1 (1)
Tension headache	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	2 (2)
Depression	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	3 (4)
Nasal congestion	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	1 (1)
Rhinitis allergic	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Boost + 28 Days completers set

Boost up to Day 28 after boost

	Older dose ranging cohorts		
System organ class Preferred term	10 µg (N=12) n (%)	Total (N=12) n (%)	Total (N=81) n (%)
Pityriasis rosea	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 10 of 10)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	60 µg (N=12) n (%)	Total (N=81) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	2 (2)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (1)
Tachycardia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (8)	2 (2)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (8)	2 (2)
Eye disorders	1 (8)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	2 (2)
Asthenopia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	1 (8)	1 (8)	1 (9)	2 (18)	1 (8)	4 (36)	2 (17)	12 (15)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (1)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Diarrhoea	1 (8)	1 (8)	1 (9)	0 (0)	1 (8)	1 (9)	0 (0)	5 (6)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	60 µg (N=12) n (%)	Total (N=81) n (%)
Dry mouth	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysphagia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (1)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gastrointestinal disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (8)	2 (2)
General disorders and administration site conditions	11 (92)	0 (0)	11 (100)	0 (0)	11 (92)	11 (100)	12 (100)	56 (69)
Chills	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	8 (67)	0 (0)	5 (45)	0 (0)	5 (42)	1 (9)	0 (0)	19 (23)
Influenza like illness	5 (42)	0 (0)	7 (64)	0 (0)	10 (83)	10 (91)	12 (100)	44 (54)
Injection site discolouration	0 (0)	0 (0)	1 (9)	0 (0)	2 (17)	0 (0)	0 (0)	3 (4)
Injection site discomfort	3 (25)	0 (0)	5 (45)	0 (0)	3 (25)	1 (9)	2 (17)	14 (17)
Injection site erythema	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	0 (0)	2 (2)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 2 of 14)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	60 µg (N=12) n (%)	Total (N=81) n (%)
Injection site hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Injection site pain	4 (33)	0 (0)	4 (36)	0 (0)	3 (25)	1 (9)	4 (33)	16 (20)
Injection site paraesthesia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	4 (33)	0 (0)	7 (64)	0 (0)	10 (83)	11 (100)	8 (67)	40 (49)
Pyrexia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	3 (25)	5 (6)
Immune system disorders	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Seasonal allergy	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	2 (18)	1 (9)	1 (8)	2 (18)	1 (8)	7 (9)
Conjunctivitis	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Fungal infection	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingivitis	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 3 of 14)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	60 µg (N=12) n (%)	Total (N=81) n (%)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (8)	2 (2)
Investigations	2 (17)	0 (0)	1 (9)	0 (0)	1 (8)	1 (9)	1 (8)	6 (7)
Body temperature increased	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Lymphocyte count increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle strength abnormal	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	3 (27)	0 (0)	6 (7)
Decreased appetite	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	3 (27)	0 (0)	6 (7)
Musculoskeletal and connective tissue disorders	1 (8)	0 (0)	2 (18)	1 (9)	3 (25)	3 (27)	0 (0)	10 (12)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	0 (0)	2 (2)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Muscle tightness	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (2)
Musculoskeletal chest pain	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	0 (0)	0 (0)	2 (2)
Musculoskeletal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	60 µg (N=12) n (%)	Total (N=81) n (%)
Myalgia	1 (8)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	0 (0)	3 (4)
Myosclerosis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (1)
Pain in extremity	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	2 (2)
Nervous system disorders	6 (50)	0 (0)	8 (73)	2 (18)	8 (67)	5 (45)	6 (50)	35 (43)
Cervicobrachial syndrome	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	1 (9)	1 (9)	1 (8)	2 (18)	0 (0)	5 (6)
Head discomfort	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
Headache	5 (42)	0 (0)	8 (73)	1 (9)	8 (67)	4 (36)	3 (25)	29 (36)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Migraine	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Paraesthesia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	1 (8)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (8)	3 (4)
Syncope	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Taste disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 5 of 14)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	60 µg (N=12) n (%)	Total (N=81) n (%)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	1 (8)	3 (4)
Depression	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (8)	2 (2)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (1)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	2 (18)	2 (18)	0 (0)	2 (18)	2 (17)	8 (10)
Cough	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	1 (8)	3 (4)
Dysphonia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	1 (9)	1 (8)	4 (5)
Rhinitis allergic	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (2)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 6 of 14)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	60 µg (N=12) n (%)	Total (N=81) n (%)
Pruritus	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	0 (0)	2 (2)
Hot flush	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 7 of 14)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts			
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=1) n (%)	Total (N=13) n (%)	Total (N=94) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	2 (2)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	1 (1)
Tachycardia	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	2 (2)
Ear pain	0 (0)	0 (0)	0 (0)	2 (2)
Eye disorders	0 (0)	0 (0)	0 (0)	2 (2)
Asthenopia	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	0 (0)	12 (13)
Abdominal pain	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain lower	0 (0)	0 (0)	0 (0)	1 (1)
Diarrhoea	0 (0)	0 (0)	0 (0)	5 (5)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 8 of 14)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts			
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=1) n (%)	Total (N=13) n (%)	Total (N=94) n (%)
Dry mouth	0 (0)	0 (0)	0 (0)	1 (1)
Dysphagia	0 (0)	0 (0)	0 (0)	1 (1)
Flatulence	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorder	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	0 (0)	0 (0)	0 (0)	2 (2)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	56 (60)
Chills	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	0 (0)	0 (0)	0 (0)	19 (20)
Influenza like illness	0 (0)	0 (0)	0 (0)	44 (47)
Injection site discolouration	0 (0)	0 (0)	0 (0)	3 (3)
Injection site discomfort	0 (0)	0 (0)	0 (0)	14 (15)
Injection site erythema	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	2 (2)
Injection site hypersensitivity	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 9 of 14)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts			
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=1) n (%)	Total (N=13) n (%)	Total (N=94) n (%)
Injection site hypoaesthesia	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	0 (0)	0 (0)	0 (0)	16 (17)
Injection site paraesthesia	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	0 (0)	0 (0)	0 (0)	40 (43)
Pyrexia	0 (0)	0 (0)	0 (0)	5 (5)
Immune system disorders	0 (0)	0 (0)	0 (0)	1 (1)
Seasonal allergy	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	7 (7)
Conjunctivitis	0 (0)	0 (0)	0 (0)	1 (1)
Fungal infection	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	0 (0)	1 (1)
Gingivitis	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 10 of 14)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts			
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=1) n (%)	Total (N=13) n (%)	Total (N=94) n (%)
Tinea pedis	0 (0)	0 (0)	0 (0)	2 (2)
Investigations	0 (0)	0 (0)	0 (0)	6 (6)
Body temperature increased	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	0 (0)	0 (0)	0 (0)	1 (1)
Muscle strength abnormal	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	6 (6)
Decreased appetite	0 (0)	0 (0)	0 (0)	6 (6)
Musculoskeletal and connective tissue disorders	0 (0)	1 (100)	1 (8)	11 (12)
Arthralgia	0 (0)	0 (0)	0 (0)	2 (2)
Back pain	0 (0)	0 (0)	0 (0)	1 (1)
Muscle tightness	0 (0)	0 (0)	0 (0)	2 (2)
Musculoskeletal chest pain	0 (0)	1 (100)	1 (8)	3 (3)
Musculoskeletal pain	0 (0)	1 (100)	1 (8)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 11 of 14)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts			
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=1) n (%)	Total (N=13) n (%)	Total (N=94) n (%)
Myalgia	0 (0)	0 (0)	0 (0)	3 (3)
Myosclerosis	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	2 (2)
Nervous system disorders	1 (8)	1 (100)	2 (15)	37 (39)
Cervicobrachial syndrome	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	0 (0)	0 (0)	0 (0)	5 (5)
Head discomfort	0 (0)	0 (0)	0 (0)	2 (2)
Headache	0 (0)	0 (0)	0 (0)	29 (31)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	1 (1)
Migraine	1 (8)	0 (0)	1 (8)	1 (1)
Paraesthesia	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	0 (0)	0 (0)	0 (0)	3 (3)
Syncope	0 (0)	1 (100)	1 (8)	1 (1)
Taste disorder	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 12 of 14)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts			
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=1) n (%)	Total (N=13) n (%)	Total (N=94) n (%)
Tension headache	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	3 (3)
Depression	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	2 (2)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	1 (1)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	2 (17)	0 (0)	2 (15)	10 (11)
Cough	2 (17)	0 (0)	2 (15)	5 (5)
Dysphonia	0 (0)	0 (0)	0 (0)	1 (1)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	4 (4)
Rhinitis allergic	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	2 (2)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 13 of 14)

Table 14.3.1-3.3.1-1: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b1

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts			
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=1) n (%)	Total (N=13) n (%)	Total (N=94) n (%)
Pruritus	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	2 (2)
Hot flush	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 14 of 14)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (2)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	3 (4)
Fatigue	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Injection site reaction	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 1 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Musculoskeletal and connective tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	3 (4)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Paraesthesia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	2 (17)	1 (8)	0 (0)	1 (8)	2 (17)	6 (7)
Cough	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	3 (4)
Dysphonia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 2 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Oropharyngeal pain	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	3 (4)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Alopecia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pruritus	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 3 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (2)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dyspepsia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	1 (8)	0 (0)	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	4 (5)
Fatigue	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Injection site paraesthesia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	3 (4)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 4 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Genital herpes	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingivitis	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Thermal burn	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Investigations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Muscle strength abnormal	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	1 (8)	0 (0)	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	4 (5)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Muscle tightness	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Myalgia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 5 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Myosclerosis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	2 (17)	5 (6)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Migraine	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Paraesthesia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Syncope	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 6 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	2 (17)	1 (8)	0 (0)	1 (8)	2 (17)	6 (7)
Cough	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
Dysphonia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	3 (4)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Alopecia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pruritus	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Surgical and medical procedures	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Papilloma excision	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 7 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Eye disorders	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	2 (2)
Asthenopia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Eye irritation	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Gastrointestinal disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Dry mouth	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
General disorders and administration site conditions	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	3 (25)	N/A	6 (7)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 8 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Influenza like illness	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Injection site pain	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Injection site reaction	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	N/A	4 (5)
Infections and infestations	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	N/A	3 (4)
Conjunctivitis	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Investigations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Lymphocyte count increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Metabolism and nutrition disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Decreased appetite	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Musculoskeletal and connective tissue disorders	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	N/A	4 (5)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 9 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	N/A	1 (1)
Muscle tightness	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Nervous system disorders	2 (17)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	N/A	4 (5)
Headache	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	N/A	2 (2)
Presyncope	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	N/A	2 (2)
Taste disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	N/A	2 (2)
Depression	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Bladder dysfunction	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	N/A	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 10 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 11 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Cardiac disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	2 (2)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Tachycardia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Eye disorders	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	2 (2)
Asthenopia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Eye irritation	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Gastrointestinal disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	2 (2)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Dry mouth	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Dysphagia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
General disorders and administration site conditions	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	3 (25)	N/A	6 (7)
Influenza like illness	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Injection site pain	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Injection site reaction	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	N/A	4 (5)
Immune system disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Seasonal allergy	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (17)	N/A	4 (5)
Conjunctivitis	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Fungal infection	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 13 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Investigations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Lymphocyte count increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Metabolism and nutrition disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Decreased appetite	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Musculoskeletal and connective tissue disorders	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	N/A	4 (5)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	N/A	1 (1)
Muscle tightness	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Nervous system disorders	3 (25)	0 (0)	2 (17)	0 (0)	0 (0)	1 (8)	N/A	6 (7)
Cervicobrachial syndrome	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Headache	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	N/A	3 (4)
Presyncope	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	N/A	2 (2)
Taste disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 14 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	N/A	2 (2)
Depression	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Bladder dysfunction	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	1 (8)	N/A	3 (4)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Rhinitis allergic	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	N/A	1 (1)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 15 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Tachycardia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	2 (2)
Asthenopia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	4 (5)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dry mouth	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 16 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Dyspepsia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dysphagia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	2 (17)	0 (0)	2 (17)	0 (0)	2 (17)	3 (25)	0 (0)	9 (11)
Fatigue	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
Injection site pain	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site paraesthesia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	2 (17)	0 (0)	5 (6)
Immune system disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Seasonal allergy	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	2 (17)	1 (8)	1 (8)	2 (17)	1 (8)	7 (8)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 17 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Conjunctivitis	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Fungal infection	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingivitis	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Thermal burn	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Investigations	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	3 (4)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Lymphocyte count increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle strength abnormal	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 18 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Metabolism and nutrition disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Decreased appetite	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	1 (8)	0 (0)	1 (8)	1 (8)	2 (17)	1 (8)	0 (0)	6 (7)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Muscle tightness	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (2)
Musculoskeletal chest pain	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	2 (2)
Musculoskeletal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Myalgia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myosclerosis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
Nervous system disorders	3 (25)	0 (0)	2 (17)	1 (8)	1 (8)	1 (8)	2 (17)	10 (12)
Cervicobrachial syndrome	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	2 (17)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	4 (5)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Migraine	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 19 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Paraesthesia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	3 (4)
Syncope	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Taste disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	1 (8)	3 (4)
Depression	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (2)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bladder dysfunction	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	3 (25)	2 (17)	0 (0)	2 (17)	2 (17)	9 (11)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts							
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Cough	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
Dysphonia	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	4 (5)
Rhinitis allergic	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (2)
Alopecia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Pruritus	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Surgical and medical procedures	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Papilloma excision	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 21 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 22 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	2 (17)	2 (6)	3 (3)
Sleep disorder	0 (0)	0 (0)	2 (17)	2 (6)	3 (3)
Renal and urinary disorders	0 (0)	0 (0)	3 (25)	3 (8)	3 (3)
Pollakiuria	0 (0)	0 (0)	3 (25)	3 (8)	3 (3)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	2 (17)	2 (6)	8 (7)
Cough	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Dysphonia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 23 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Oropharyngeal pain	0 (0)	0 (0)	2 (17)	2 (6)	5 (4)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Alopecia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pruritus	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 24 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Ear pain	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Gastrointestinal disorders	0 (0)	0 (0)	2 (17)	2 (6)	4 (3)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Dyspepsia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 25 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Genital herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingivitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Thermal burn	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle strength abnormal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	0 (0)	1 (8)	0 (0)	1 (3)	5 (4)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle tightness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
Musculoskeletal pain	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Myosclerosis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	1 (8)	1 (8)	0 (0)	2 (6)	7 (6)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Migraine	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Syncope	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	2 (17)	2 (6)	3 (3)
Sleep disorder	0 (0)	0 (0)	2 (17)	2 (6)	3 (3)
Renal and urinary disorders	0 (0)	0 (0)	3 (25)	3 (8)	3 (3)
Pollakiuria	0 (0)	0 (0)	3 (25)	3 (8)	3 (3)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 27 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Respiratory, thoracic and mediastinal disorders	2 (17)	0 (0)	2 (17)	4 (11)	10 (8)
Cough	2 (17)	0 (0)	0 (0)	2 (6)	6 (5)
Dysphonia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	2 (17)	2 (6)	5 (4)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Alopecia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pruritus	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Surgical and medical procedures	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Papilloma excision	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 28 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Asthenopia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Dry mouth	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 29 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Infections and infestations	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)
Conjunctivitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle tightness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Taste disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Depression	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Bladder dysfunction	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 31 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tachycardia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Asthenopia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Dry mouth	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Dysphagia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Immune system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Seasonal allergy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	1 (8)	1 (3)	5 (4)
Conjunctivitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fungal infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 34 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle tightness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
Cervicobrachial syndrome	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Taste disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 35 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Depression	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Bladder dysfunction	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis allergic	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 36 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tachycardia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Ear pain	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Asthenopia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	2 (17)	2 (6)	6 (5)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Dry mouth	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 37 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Dyspepsia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Dysphagia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Flatulence	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	9 (8)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
Immune system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Seasonal allergy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	2 (17)	2 (6)	9 (8)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Conjunctivitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fungal infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingivitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Injury, poisoning and procedural complications	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Thermal burn	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Gamma-glutamyltransferase increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle strength abnormal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 39 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	0 (0)	1 (8)	0 (0)	1 (3)	7 (6)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle tightness	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Musculoskeletal chest pain	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
Musculoskeletal pain	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myosclerosis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Nervous system disorders	1 (8)	1 (8)	0 (0)	2 (6)	12 (10)
Cervicobrachial syndrome	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Hyperaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Migraine	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Syncope	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Taste disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	2 (17)	2 (6)	5 (4)
Depression	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	2 (17)	2 (6)	4 (3)
Renal and urinary disorders	0 (0)	0 (0)	3 (25)	3 (8)	3 (3)
Bladder dysfunction	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pollakiuria	0 (0)	0 (0)	3 (25)	3 (8)	3 (3)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Respiratory, thoracic and mediastinal disorders	2 (17)	0 (0)	2 (17)	4 (11)	13 (11)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Cough	2 (17)	0 (0)	0 (0)	2 (6)	6 (5)
Dysphonia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	2 (17)	2 (6)	6 (5)
Rhinitis allergic	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Alopecia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pruritus	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Surgical and medical procedures	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Papilloma excision	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 42 of 42)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 7 after prime

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Gastrointestinal disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Gingival pain	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (3)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Paraesthesia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Sleep disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 1 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 7 after prime

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	1 (9)	3 (4)
Cough	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	2 (3)
Dysphonia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	0 (0)	2 (3)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Alopecia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pruritus	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 2 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Gastrointestinal disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dyspepsia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Gingival pain	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	1 (8)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	3 (4)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Injection site paraesthesia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	0 (0)	2 (3)
Genital herpes	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Gingivitis	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 3 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Thermal burn	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Investigations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle strength abnormal	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	1 (8)	0 (0)	1 (9)	0 (0)	2 (17)	0 (0)	4 (6)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Muscle tightness	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Myalgia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myosclerosis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	1 (9)	1 (8)	1 (9)	3 (4)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Migraine	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Paraesthesia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 4 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Sleep disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	1 (9)	3 (4)
Cough	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	2 (3)
Dysphonia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	0 (0)	2 (3)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Alopecia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pruritus	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 5 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	1 (8)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (3)
Asthenopia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dry mouth	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	2 (17)	0 (0)	1 (9)	0 (0)	0 (0)	3 (27)	6 (9)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 6 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Influenza like illness	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Injection site pain	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	1 (8)	0 (0)	1 (9)	0 (0)	0 (0)	2 (18)	4 (6)
Infections and infestations	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	2 (18)	3 (4)
Conjunctivitis	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Investigations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Decreased appetite	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	1 (8)	0 (0)	0 (0)	1 (9)	1 (8)	1 (9)	4 (6)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 7 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Muscle tightness	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nervous system disorders	2 (17)	0 (0)	2 (18)	0 (0)	0 (0)	0 (0)	4 (6)
Headache	1 (8)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	2 (3)
Presyncope	1 (8)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	2 (3)
Taste disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Depression	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bladder dysfunction	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (9)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 8 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 9 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Cardiac disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	2 (3)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Tachycardia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	1 (8)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (3)
Asthenopia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	2 (3)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dry mouth	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 10 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Dysphagia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
General disorders and administration site conditions	2 (17)	0 (0)	1 (9)	0 (0)	0 (0)	3 (27)	6 (9)
Influenza like illness	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Injection site pain	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	1 (8)	0 (0)	1 (9)	0 (0)	0 (0)	2 (18)	4 (6)
Immune system disorders	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Seasonal allergy	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	1 (9)	1 (8)	2 (18)	4 (6)
Conjunctivitis	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Fungal infection	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 11 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Investigations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Decreased appetite	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	1 (8)	0 (0)	0 (0)	1 (9)	1 (8)	1 (9)	4 (6)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Muscle tightness	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nervous system disorders	3 (25)	0 (0)	2 (18)	0 (0)	0 (0)	1 (9)	6 (9)
Cervicobrachial syndrome	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	2 (17)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	3 (4)
Presyncope	1 (8)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	2 (3)
Taste disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 12 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Depression	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bladder dysfunction	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	1 (9)	3 (4)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Rhinitis allergic	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 13 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Cardiac disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	2 (3)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Tachycardia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Vertigo	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	1 (8)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (3)
Asthenopia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	1 (8)	0 (0)	0 (0)	1 (9)	0 (0)	1 (9)	3 (4)
Abdominal pain upper	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dry mouth	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 14 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Dyspepsia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dysphagia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	2 (17)	0 (0)	1 (9)	0 (0)	2 (17)	3 (27)	8 (12)
Influenza like illness	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	2 (3)
Injection site pain	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site paraesthesia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	1 (8)	0 (0)	1 (9)	0 (0)	0 (0)	2 (18)	4 (6)
Immune system disorders	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Seasonal allergy	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	2 (18)	1 (9)	1 (8)	2 (18)	6 (9)
Conjunctivitis	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Fungal infection	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 15 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Genital herpes	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Gingivitis	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Thermal burn	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Investigations	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (3)
Lymphocyte count increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle strength abnormal	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Decreased appetite	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	1 (8)	0 (0)	1 (9)	1 (9)	2 (17)	1 (9)	6 (9)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 16 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Muscle tightness	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (3)
Musculoskeletal chest pain	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	0 (0)	2 (3)
Myalgia	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myosclerosis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	2 (3)
Nervous system disorders	3 (25)	0 (0)	2 (18)	1 (9)	1 (8)	1 (9)	8 (12)
Cervicobrachial syndrome	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	2 (17)	0 (0)	1 (9)	0 (0)	1 (8)	0 (0)	4 (6)
Migraine	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Paraesthesia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Presyncope	1 (8)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	2 (3)
Taste disorder	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 17 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Depression	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bladder dysfunction	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	2 (18)	2 (18)	0 (0)	2 (18)	6 (9)
Cough	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	2 (3)
Dysphonia	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	1 (9)	3 (4)
Rhinitis allergic	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 18 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts						
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Alopecia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Pruritus	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 19 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Gastrointestinal disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Sleep disorder	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Renal and urinary disorders	0 (0)	0 (0)	3 (25)	3 (9)	3 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Pollakiuria	0 (0)	0 (0)	3 (25)	3 (9)	3 (3)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	2 (17)	2 (6)	5 (5)
Cough	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Dysphonia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Alopecia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pruritus	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 21 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Ear pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	2 (17)	2 (6)	3 (3)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Dyspepsia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Genital herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingivitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Injury, poisoning and procedural complications	0 (0)	1 (9)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 22 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Thermal burn	0 (0)	1 (9)	0 (0)	1 (3)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle strength abnormal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle tightness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myosclerosis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	1 (8)	0 (0)	0 (0)	1 (3)	4 (4)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Migraine	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Psychiatric disorders	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Sleep disorder	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Renal and urinary disorders	0 (0)	0 (0)	3 (25)	3 (9)	3 (3)
Pollakiuria	0 (0)	0 (0)	3 (25)	3 (9)	3 (3)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	2 (17)	0 (0)	2 (17)	4 (11)	7 (7)
Cough	2 (17)	0 (0)	0 (0)	2 (6)	4 (4)
Dysphonia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Alopecia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pruritus	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Asthenopia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Dry mouth	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 25 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Infections and infestations	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
Conjunctivitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle tightness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Taste disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Depression	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Bladder dysfunction	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 28 of 38)

Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tachycardia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Ear pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Asthenopia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Dry mouth	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Dysphagia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Immune system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Seasonal allergy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	1 (8)	1 (3)	5 (5)
Conjunctivitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fungal infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle tightness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
Cervicobrachial syndrome	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Taste disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Depression	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Bladder dysfunction	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis allergic	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Cardiovascular disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tachycardia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Ear pain	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Vertigo	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Asthenopia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	2 (17)	2 (6)	5 (5)
Abdominal pain upper	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Dry mouth	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Dyspepsia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Dysphagia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	8 (8)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site discolouration	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Immune system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Seasonal allergy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	2 (17)	2 (6)	8 (8)
Conjunctivitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fungal infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Genital herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingivitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tinea pedis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	0 (0)	1 (9)	0 (0)	1 (3)	1 (1)
Thermal burn	0 (0)	1 (9)	0 (0)	1 (3)	1 (1)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Lymphocyte count increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle strength abnormal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Decreased appetite	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle tightness	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Musculoskeletal chest pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myosclerosis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Nervous system disorders	1 (8)	0 (0)	0 (0)	1 (3)	9 (9)
Cervicobrachial syndrome	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Migraine	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Paraesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Taste disorder	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tension headache	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Depression	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	0 (0)	0 (0)	2 (17)	2 (6)	3 (3)
Renal and urinary disorders	0 (0)	0 (0)	3 (25)	3 (9)	3 (3)
Bladder dysfunction	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pollakiuria	0 (0)	0 (0)	3 (25)	3 (9)	3 (3)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	2 (17)	0 (0)	2 (17)	4 (11)	10 (10)
Cough	2 (17)	0 (0)	0 (0)	2 (6)	4 (4)
Dysphonia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	2 (17)	2 (6)	5 (5)
Rhinitis allergic	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-1: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Alopecia	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pityriasis rosea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pruritus	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Ear pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gastrointestinal disorders	Any	1 (8)	1 (8)	2 (17)	2 (17)	1 (8)	1 (8)	2 (17)	10 (12)
Abdominal pain lower	Mild	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	Mild	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	4 (5)
	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Flatulence	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gastrointestinal disorder	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	Moderate	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
General disorders and administration site conditions	Any	10 (83)	0 (0)	10 (83)	0 (0)	11 (92)	12 (100)	12 (100)	55 (65)
Chills	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Fatigue	Mild	7 (58)	0 (0)	5 (42)	0 (0)	5 (42)	1 (8)	0 (0)	18 (21)
	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	Mild	2 (17)	0 (0)	0 (0)	0 (0)	2 (17)	4 (33)	3 (25)	11 (13)
	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	4 (33)	7 (58)	9 (75)	21 (25)
Injection site discolouration	Mild	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	3 (4)
Injection site discomfort	Mild	3 (25)	0 (0)	2 (17)	0 (0)	1 (8)	1 (8)	2 (17)	9 (11)
Injection site erythema	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Injection site hypersensitivity	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Injection site hypoaesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Injection site pain	Mild	2 (17)	0 (0)	3 (25)	0 (0)	3 (25)	1 (8)	3 (25)	12 (14)
Injection site reaction	Mild	2 (17)	0 (0)	4 (33)	0 (0)	7 (58)	4 (33)	3 (25)	20 (24)
	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	3 (25)	5 (42)	5 (42)	14 (17)
Pyrexia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	1 (8)	3 (4)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Pyrexia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Infections and infestations	Any	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	Any	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	1 (8)	4 (5)
Body temperature increased	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Metabolism and nutrition disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
Decreased appetite	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
Musculoskeletal and connective tissue disorders	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	3 (4)
Arthralgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Neck pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Pain in extremity	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Nervous system disorders	Any	4 (33)	0 (0)	6 (50)	1 (8)	7 (58)	4 (33)	6 (50)	28 (33)
Dizziness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Head discomfort	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
Headache	Mild	2 (17)	0 (0)	3 (25)	0 (0)	6 (50)	1 (8)	1 (8)	13 (15)
	Moderate	2 (17)	0 (0)	2 (17)	0 (0)	1 (8)	3 (25)	2 (17)	10 (12)
Hyperaesthesia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Paraesthesia	Mild	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Sleep disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Renal and urinary disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	0 (0)	2 (17)	1 (8)	0 (0)	1 (8)	2 (17)	6 (7)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Cough	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Dysphonia	Mild	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	3 (4)
Skin and subcutaneous tissue disorders	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Alopecia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pruritus	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Ear pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gastrointestinal disorders	Any	1 (8)	1 (8)	2 (17)	2 (17)	1 (8)	1 (8)	2 (17)	10 (12)
Abdominal pain lower	Mild	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	Mild	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	4 (5)
	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspepsia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Flatulence	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gastrointestinal disorder	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	Moderate	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
General disorders and administration site conditions	Any	11 (92)	0 (0)	10 (83)	0 (0)	11 (92)	12 (100)	12 (100)	56 (67)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Chills	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	Mild	7 (58)	0 (0)	5 (42)	0 (0)	5 (42)	1 (8)	0 (0)	18 (21)
	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	Mild	2 (17)	0 (0)	0 (0)	0 (0)	2 (17)	4 (33)	3 (25)	11 (13)
	Moderate	1 (8)	0 (0)	1 (8)	0 (0)	4 (33)	7 (58)	9 (75)	22 (26)
Injection site discolouration	Mild	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	3 (4)
Injection site discomfort	Mild	3 (25)	0 (0)	2 (17)	0 (0)	1 (8)	1 (8)	2 (17)	9 (11)
Injection site erythema	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Injection site hypersensitivity	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Injection site hypoaesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Injection site pain	Mild	3 (25)	0 (0)	3 (25)	0 (0)	3 (25)	1 (8)	4 (33)	14 (17)
Injection site paraesthesia	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Injection site reaction	Mild	3 (25)	0 (0)	4 (33)	0 (0)	7 (58)	4 (33)	3 (25)	21 (25)
	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	3 (25)	5 (42)	5 (42)	14 (17)
Malaise	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pyrexia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	1 (8)	3 (4)
	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Infections and infestations	Any	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	3 (4)
Genital herpes	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingivitis	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Tinea pedis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Injury, poisoning and procedural complications	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Thermal burn	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Investigations	Any	1 (8)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	1 (8)	5 (6)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Body temperature increased	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Muscle strength abnormal	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	Any	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	3 (4)
Decreased appetite	Mild	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	3 (4)
Musculoskeletal and connective tissue disorders	Any	1 (8)	0 (0)	2 (17)	0 (0)	2 (17)	2 (17)	0 (0)	7 (8)
Arthralgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Back pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Muscle tightness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Myalgia	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Myalgia	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myosclerosis	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Pain in extremity	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	Any	4 (33)	0 (0)	6 (50)	1 (8)	7 (58)	5 (42)	6 (50)	29 (35)
Dizziness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Head discomfort	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
Headache	Mild	2 (17)	0 (0)	3 (25)	0 (0)	6 (50)	1 (8)	1 (8)	13 (15)
	Moderate	2 (17)	0 (0)	2 (17)	0 (0)	1 (8)	3 (25)	2 (17)	10 (12)
	Severe	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Hyperaesthesia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Migraine	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Paraesthesia	Mild	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Syncope	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Tension headache	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Sleep disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Renal and urinary disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Reproductive system and breast disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
Dysmenorrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	0 (0)	2 (17)	1 (8)	0 (0)	1 (8)	2 (17)	6 (7)
Cough	Mild	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	3 (4)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Dysphonia	Mild	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Oropharyngeal pain	Mild	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	3 (4)
Skin and subcutaneous tissue disorders	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Alopecia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pruritus	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Surgical and medical procedures	Any	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Papilloma excision	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Blood and lymphatic system disorders	Any	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Lymphadenopathy	Moderate	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Cardiac disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Cardiovascular disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Ear pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Vertigo	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Eye disorders	Any	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	2 (2)
Asthenopia	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Eye irritation	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Photophobia	Severe	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Gastrointestinal disorders	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	N/A	3 (4)
Abdominal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Abdominal pain upper	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Dry mouth	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Vomiting	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
General disorders and administration site conditions	Any	7 (58)	0 (0)	11 (92)	0 (0)	11 (92)	11 (92)	N/A	40 (48)
Fatigue	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Influenza like illness	Mild	0 (0)	0 (0)	2 (17)	0 (0)	3 (25)	2 (17)	N/A	7 (8)
	Moderate	5 (42)	0 (0)	4 (33)	0 (0)	7 (58)	6 (50)	N/A	22 (26)
	Severe	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	N/A	3 (4)
Injection site discomfort	Mild	1 (8)	0 (0)	3 (25)	0 (0)	2 (17)	0 (0)	N/A	6 (7)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	N/A	1 (1)
Injection site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Injection site pain	Mild	2 (17)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	N/A	4 (5)
	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Injection site reaction	Mild	1 (8)	0 (0)	4 (33)	0 (0)	2 (17)	5 (42)	N/A	12 (14)
	Moderate	3 (25)	0 (0)	2 (17)	0 (0)	6 (50)	6 (50)	N/A	17 (20)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Infections and infestations	Any	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	N/A	3 (4)
Conjunctivitis	Moderate	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Nasal herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Nasopharyngitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Oral herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Tinea pedis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Investigations	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Lymphocyte count increased	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Metabolism and nutrition disorders	Any	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	N/A	4 (5)
Decreased appetite	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	N/A	3 (4)
Musculoskeletal and connective tissue disorders	Any	1 (8)	0 (0)	1 (8)	1 (8)	1 (8)	2 (17)	N/A	6 (7)
Arthralgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Back pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Muscle tightness	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Musculoskeletal chest pain	Severe	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Myalgia	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	N/A	2 (2)
Pain in extremity	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Nervous system disorders	Any	4 (33)	0 (0)	5 (42)	1 (8)	3 (25)	3 (25)	N/A	16 (19)
Dizziness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	N/A	2 (2)
	Severe	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Headache	Mild	0 (0)	0 (0)	3 (25)	0 (0)	2 (17)	0 (0)	N/A	5 (6)
	Moderate	3 (25)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	N/A	6 (7)
Presyncope	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Taste disorder	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	N/A	2 (2)
Depression	Severe	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Hallucination	Severe	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Sleep disorder	Moderate	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Renal and urinary disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Bladder dysfunction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	N/A	2 (2)
Nasal congestion	Moderate	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Hot flush	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Blood and lymphatic system disorders	Any	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Lymphadenopathy	Moderate	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Cardiac disorders	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	2 (2)
Cardiovascular disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Tachycardia	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Ear pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Vertigo	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Eye disorders	Any	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	2 (2)
Asthenopia	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Eye irritation	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Photophobia	Severe	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Gastrointestinal disorders	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	4 (33)	N/A	5 (6)
Abdominal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Abdominal pain upper	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Diarrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Dry mouth	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Dysphagia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Vomiting	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
General disorders and administration site conditions	Any	7 (58)	0 (0)	11 (92)	0 (0)	11 (92)	11 (92)	N/A	40 (48)
Fatigue	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Influenza like illness	Mild	0 (0)	0 (0)	2 (17)	0 (0)	3 (25)	2 (17)	N/A	7 (8)
	Moderate	5 (42)	0 (0)	4 (33)	0 (0)	7 (58)	6 (50)	N/A	22 (26)
	Severe	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	N/A	3 (4)
Injection site discomfort	Mild	1 (8)	0 (0)	3 (25)	0 (0)	2 (17)	0 (0)	N/A	6 (7)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	N/A	1 (1)
Injection site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Injection site pain	Mild	2 (17)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	N/A	4 (5)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Injection site pain	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Injection site reaction	Mild	1 (8)	0 (0)	4 (33)	0 (0)	2 (17)	5 (42)	N/A	12 (14)
	Moderate	3 (25)	0 (0)	2 (17)	0 (0)	6 (50)	6 (50)	N/A	17 (20)
Immune system disorders	Any	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Seasonal allergy	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Infections and infestations	Any	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (17)	N/A	4 (5)
Conjunctivitis	Moderate	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Fungal infection	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Nasal herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Nasopharyngitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Oral herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Rhinitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	N/A	1 (1)
Tinea pedis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Investigations	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Lymphocyte count increased	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Metabolism and nutrition disorders	Any	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	N/A	4 (5)
Decreased appetite	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	N/A	3 (4)
Musculoskeletal and connective tissue disorders	Any	1 (8)	0 (0)	1 (8)	1 (8)	2 (17)	2 (17)	N/A	7 (8)
Arthralgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	N/A	2 (2)
Back pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	N/A	1 (1)
Muscle tightness	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Musculoskeletal chest pain	Severe	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Myalgia	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	N/A	2 (2)
Pain in extremity	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Nervous system disorders	Any	5 (42)	0 (0)	7 (58)	2 (17)	4 (33)	3 (25)	N/A	21 (25)
Cervicobrachial syndrome	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Dizziness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	N/A	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Dizziness	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
	Severe	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Headache	Mild	0 (0)	0 (0)	2 (17)	0 (0)	2 (17)	0 (0)	N/A	4 (5)
	Moderate	4 (33)	0 (0)	4 (33)	1 (8)	2 (17)	1 (8)	N/A	12 (14)
Presyncope	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Taste disorder	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Tension headache	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	N/A	2 (2)
Depression	Severe	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Hallucination	Severe	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Sleep disorder	Moderate	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Renal and urinary disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)
Bladder dysfunction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	N/A	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	1 (8)	N/A	3 (4)
Nasal congestion	Moderate	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	N/A	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Rhinitis allergic	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	N/A	1 (1)
Skin and subcutaneous tissue disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	N/A	1 (1)
Pityriasis rosea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	N/A	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)
Hot flush	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	N/A	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Blood and lymphatic system disorders	Any	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	Moderate	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
Cardiovascular disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Tachycardia	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
Ear pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
Vertigo	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	Any	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	2 (2)
Asthenopia	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	Severe	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	Any	1 (8)	1 (8)	2 (17)	2 (17)	1 (8)	4 (33)	2 (17)	13 (15)
Abdominal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Abdominal pain lower	Mild	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	Mild	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	0 (0)	5 (6)
	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dry mouth	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspepsia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dysphagia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Flatulence	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Gastrointestinal disorder	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	Moderate	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
General disorders and administration site conditions	Any	11 (92)	0 (0)	12 (100)	0 (0)	11 (92)	12 (100)	12 (100)	58 (69)
Chills	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Chills	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	Mild	7 (58)	0 (0)	5 (42)	0 (0)	5 (42)	1 (8)	0 (0)	18 (21)
	Moderate	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Influenza like illness	Mild	0 (0)	0 (0)	2 (17)	0 (0)	3 (25)	3 (25)	3 (25)	11 (13)
	Moderate	5 (42)	0 (0)	5 (42)	0 (0)	7 (58)	6 (50)	9 (75)	32 (38)
	Severe	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	0 (0)	3 (4)
Injection site discolouration	Mild	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	3 (4)
Injection site discomfort	Mild	3 (25)	0 (0)	5 (42)	0 (0)	2 (17)	1 (8)	2 (17)	13 (15)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Injection site erythema	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
Injection site hypersensitivity	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Injection site hypoaesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Injection site pain	Mild	3 (25)	0 (0)	4 (33)	0 (0)	3 (25)	1 (8)	4 (33)	15 (18)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Injection site pain	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site paraesthesia	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	Mild	1 (8)	0 (0)	5 (42)	0 (0)	3 (25)	4 (33)	3 (25)	16 (19)
	Moderate	3 (25)	0 (0)	3 (25)	0 (0)	7 (58)	8 (67)	5 (42)	26 (31)
Malaise	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pyrexia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	1 (8)	3 (4)
	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Immune system disorders	Any	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Seasonal allergy	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	Any	0 (0)	0 (0)	2 (17)	1 (8)	1 (8)	2 (17)	1 (8)	7 (8)
Conjunctivitis	Moderate	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Fungal infection	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Genital herpes	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Gingivitis	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Nasopharyngitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Oral herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Rhinitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Tinea pedis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
Injury, poisoning and procedural complications	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Thermal burn	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Investigations	Any	2 (17)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	1 (8)	6 (7)
Body temperature increased	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
Lymphocyte count increased	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle strength abnormal	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Metabolism and nutrition disorders	Any	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	3 (25)	0 (0)	6 (7)
Decreased appetite	Mild	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	3 (4)
	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	3 (4)
Musculoskeletal and connective tissue disorders	Any	1 (8)	0 (0)	3 (25)	1 (8)	3 (25)	3 (25)	0 (0)	11 (13)
Arthralgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
Back pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Muscle tightness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Severe	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Myalgia	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	3 (4)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Myosclerosis	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Pain in extremity	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Nervous system disorders	Any	6 (50)	0 (0)	8 (67)	2 (17)	8 (67)	6 (50)	6 (50)	36 (43)
Cervicobrachial syndrome	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	0 (0)	3 (4)
	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Severe	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Head discomfort	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
Headache	Mild	1 (8)	0 (0)	4 (33)	0 (0)	5 (42)	1 (8)	1 (8)	12 (14)
	Moderate	4 (33)	0 (0)	4 (33)	0 (0)	3 (25)	4 (33)	2 (17)	17 (20)
	Severe	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Hyperaesthesia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Migraine	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Paraesthesia	Mild	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
Syncope	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Taste disorder	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tension headache	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	1 (8)	3 (4)
Depression	Severe	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	Severe	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bladder dysfunction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Pollakiuria	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Reproductive system and breast disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
Dysmenorrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	0 (0)	3 (25)	2 (17)	0 (0)	2 (17)	2 (17)	9 (11)
Cough	Mild	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	3 (4)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Dysphonia	Mild	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal congestion	Moderate	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	4 (5)
Rhinitis allergic	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	Any	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (2)
Alopecia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts							
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Pityriasis rosea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Pruritus	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Surgical and medical procedures	Any	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Papilloma excision	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
Hot flush	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	11 (9)
Abdominal pain lower	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Flatulence	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	Any	0 (0)	0 (0)	0 (0)	0 (0)	55 (46)
Chills	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Fatigue	Mild	0 (0)	0 (0)	0 (0)	0 (0)	18 (15)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	11 (9)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	21 (18)
Injection site discolouration	Mild	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site discomfort	Mild	0 (0)	0 (0)	0 (0)	0 (0)	9 (8)
Injection site erythema	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypersensitivity	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypoaesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	12 (10)
Injection site reaction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	20 (17)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	14 (12)
Pyrexia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Pyrexia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	Any	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Body temperature increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Decreased appetite	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Musculoskeletal and connective tissue disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Arthralgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Nervous system disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	29 (24)
Dizziness	Mild	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Head discomfort	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Headache	Mild	0 (0)	0 (0)	0 (0)	0 (0)	13 (11)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	10 (8)
Hyperaesthesia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Paraesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	2 (17)	2 (6)	3 (3)
Sleep disorder	Mild	0 (0)	0 (0)	2 (17)	2 (6)	3 (3)
Renal and urinary disorders	Any	0 (0)	0 (0)	3 (25)	3 (8)	3 (3)
Pollakiuria	Mild	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	0 (0)	2 (17)	2 (6)	8 (7)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 7 after prime

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Cough	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysphonia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	2 (17)	2 (6)	5 (4)
Skin and subcutaneous tissue disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Alopecia	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pruritus	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Ear pain	Mild	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Gastrointestinal disorders	Any	0 (0)	0 (0)	2 (17)	2 (6)	12 (10)
Abdominal pain lower	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspepsia	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Flatulence	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	Any	0 (0)	0 (0)	0 (0)	0 (0)	56 (47)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Chills	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	Mild	0 (0)	0 (0)	0 (0)	0 (0)	18 (15)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	11 (9)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	22 (18)
Injection site discolouration	Mild	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site discomfort	Mild	0 (0)	0 (0)	0 (0)	0 (0)	9 (8)
Injection site erythema	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypersensitivity	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypoaesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	14 (12)
Injection site paraesthesia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Injection site reaction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	21 (18)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	14 (12)
Malaise	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pyrexia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	Any	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)
Genital herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingivitis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Tinea pedis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	Any	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Thermal burn	Mild	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Investigations	Any	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Body temperature increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle strength abnormal	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Decreased appetite	Mild	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Musculoskeletal and connective tissue disorders	Any	0 (0)	1 (8)	0 (0)	1 (3)	8 (7)
Arthralgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Back pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle tightness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal pain	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Myalgia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Myalgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myosclerosis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	Any	1 (8)	1 (8)	1 (8)	3 (8)	32 (27)
Dizziness	Mild	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Head discomfort	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Headache	Mild	0 (0)	0 (0)	0 (0)	0 (0)	13 (11)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	10 (8)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hyperaesthesia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Migraine	Severe	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Paraesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Syncope	Severe	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Tension headache	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	2 (17)	2 (6)	3 (3)
Sleep disorder	Mild	0 (0)	0 (0)	2 (17)	2 (6)	3 (3)
Renal and urinary disorders	Any	0 (0)	0 (0)	3 (25)	3 (8)	3 (3)
Pollakiuria	Mild	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Reproductive system and breast disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Dysmenorrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Respiratory, thoracic and mediastinal disorders	Any	2 (17)	0 (0)	2 (17)	4 (11)	10 (8)
Cough	Mild	1 (8)	0 (0)	0 (0)	1 (3)	4 (3)
	Moderate	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Dysphonia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Oropharyngeal pain	Mild	0 (0)	0 (0)	2 (17)	2 (6)	5 (4)
Skin and subcutaneous tissue disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Alopecia	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pruritus	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Surgical and medical procedures	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Papilloma excision	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Blood and lymphatic system disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiovascular disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Ear pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vertigo	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Asthenopia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)
Abdominal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Dry mouth	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	Any	0 (0)	0 (0)	0 (0)	0 (0)	40 (33)
Fatigue	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	7 (6)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	22 (18)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site discomfort	Mild	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	12 (10)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	17 (14)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Infections and infestations	Any	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)
Conjunctivitis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Oral herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tinea pedis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Decreased appetite	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Musculoskeletal and connective tissue disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
Arthralgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Back pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Muscle tightness	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myalgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Pain in extremity	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	16 (13)
Dizziness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	Mild	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
Presyncope	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Taste disorder	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Depression	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Boost up to Day 7 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Hallucination	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Bladder dysfunction	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Nasal congestion	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Blood and lymphatic system disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Cardiovascular disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tachycardia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Ear pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vertigo	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Asthenopia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	6 (5)
Abdominal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Abdominal pain upper	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dry mouth	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysphagia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	Any	0 (0)	0 (0)	0 (0)	0 (0)	40 (33)
Fatigue	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	7 (6)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	22 (18)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site discomfort	Mild	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Injection site pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	12 (10)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	17 (14)
Immune system disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Seasonal allergy	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	Any	0 (0)	0 (0)	1 (8)	1 (3)	5 (4)
Conjunctivitis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fungal infection	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Oral herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tinea pedis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Lymphocyte count increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Decreased appetite	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Musculoskeletal and connective tissue disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	7 (6)
Arthralgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Back pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle tightness	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myalgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Pain in extremity	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	21 (18)
Cervicobrachial syndrome	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Dizziness	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	Mild	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	12 (10)
Presyncope	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Taste disorder	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tension headache	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Depression	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Bladder dysfunction	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Boost up to Day 28 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Nasal congestion	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis allergic	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pityriasis rosea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Blood and lymphatic system disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Cardiovascular disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tachycardia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Ear pain	Mild	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Vertigo	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Asthenopia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	Any	0 (0)	0 (0)	2 (17)	2 (6)	15 (13)
Abdominal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Abdominal pain lower	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dry mouth	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspepsia	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Dysphagia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Flatulence	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	Any	0 (0)	0 (0)	0 (0)	0 (0)	58 (48)
Chills	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Chills	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	Mild	0 (0)	0 (0)	0 (0)	0 (0)	18 (15)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Influenza like illness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	11 (9)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	32 (27)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site discolouration	Mild	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site discomfort	Mild	0 (0)	0 (0)	0 (0)	0 (0)	13 (11)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site erythema	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Injection site hypersensitivity	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypoaesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	15 (13)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Injection site pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site paraesthesia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	16 (13)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	26 (22)
Malaise	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pyrexia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Immune system disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Seasonal allergy	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	Any	0 (0)	0 (0)	2 (17)	2 (6)	9 (8)
Conjunctivitis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fungal infection	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Gingivitis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	Mild	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Oral herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tinea pedis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Injury, poisoning and procedural complications	Any	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Thermal burn	Mild	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Investigations	Any	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
Body temperature increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Gamma-glutamyltransferase increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle strength abnormal	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Metabolism and nutrition disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
Decreased appetite	Mild	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Musculoskeletal and connective tissue disorders	Any	0 (0)	1 (8)	0 (0)	1 (3)	12 (10)
Arthralgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Back pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle tightness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal pain	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Myalgia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Myosclerosis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	Any	1 (8)	1 (8)	1 (8)	3 (8)	39 (33)
Cervicobrachial syndrome	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	Mild	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Head discomfort	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Headache	Mild	0 (0)	0 (0)	0 (0)	0 (0)	12 (10)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	17 (14)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hyperaesthesia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Migraine	Severe	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Paraesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Syncope	Severe	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Taste disorder	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tension headache	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	2 (17)	2 (6)	5 (4)
Depression	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	Mild	0 (0)	0 (0)	2 (17)	2 (6)	3 (3)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	Any	0 (0)	0 (0)	3 (25)	3 (8)	3 (3)
Bladder dysfunction	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Pollakiuria	Mild	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Reproductive system and breast disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Dysmenorrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Respiratory, thoracic and mediastinal disorders	Any	2 (17)	0 (0)	2 (17)	4 (11)	13 (11)
Cough	Mild	1 (8)	0 (0)	0 (0)	1 (3)	4 (3)
	Moderate	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Dysphonia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspnoea exertional	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal congestion	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	2 (17)	2 (6)	6 (5)
Rhinitis allergic	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Alopecia	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Pityriasis rosea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pruritus	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Surgical and medical procedures	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Papilloma excision	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Hot flush	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 7 after prime

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Gastrointestinal disorders	Any	1 (8)	1 (8)	1 (9)	2 (18)	1 (8)	1 (9)	7 (10)
Abdominal pain lower	Mild	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	Mild	1 (8)	1 (8)	1 (9)	0 (0)	1 (8)	0 (0)	4 (6)
Gastrointestinal disorder	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	Moderate	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Vomiting	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
General disorders and administration site conditions	Any	10 (83)	0 (0)	9 (82)	0 (0)	11 (92)	11 (100)	41 (59)
Chills	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	Mild	7 (58)	0 (0)	4 (36)	0 (0)	5 (42)	1 (9)	17 (25)
	Moderate	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	Mild	2 (17)	0 (0)	0 (0)	0 (0)	2 (17)	3 (27)	7 (10)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	4 (33)	7 (64)	11 (16)
Injection site discolouration	Mild	0 (0)	0 (0)	1 (9)	0 (0)	2 (17)	0 (0)	3 (4)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 7 after prime

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Injection site discomfort	Mild	3 (25)	0 (0)	2 (18)	0 (0)	1 (8)	1 (9)	7 (10)
Injection site erythema	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Injection site hypersensitivity	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Injection site pain	Mild	2 (17)	0 (0)	3 (27)	0 (0)	3 (25)	1 (9)	9 (13)
Injection site reaction	Mild	2 (17)	0 (0)	4 (36)	0 (0)	7 (58)	4 (36)	17 (25)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	4 (36)	7 (10)
Pyrexia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	2 (3)
Infections and infestations	Any	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	Any	0 (0)	0 (0)	1 (9)	0 (0)	1 (8)	1 (9)	3 (4)
Body temperature increased	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	2 (3)
Metabolism and nutrition disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 7 after prime

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Decreased appetite	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	2 (3)
Musculoskeletal and connective tissue disorders	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	3 (4)
Arthralgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Neck pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Pain in extremity	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	Any	4 (33)	0 (0)	6 (55)	1 (9)	7 (58)	3 (27)	21 (30)
Dizziness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Head discomfort	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	Mild	2 (17)	0 (0)	3 (27)	0 (0)	6 (50)	1 (9)	12 (17)
	Moderate	2 (17)	0 (0)	2 (18)	0 (0)	1 (8)	2 (18)	7 (10)
Paraesthesia	Mild	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Sleep disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 7 after prime

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Pollakiuria	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	1 (9)	3 (4)
Cough	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Dysphonia	Mild	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	0 (0)	2 (3)
Skin and subcutaneous tissue disorders	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Alopecia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pruritus	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Ear pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Gastrointestinal disorders	Any	1 (8)	1 (8)	1 (9)	2 (18)	1 (8)	1 (9)	7 (10)
Abdominal pain lower	Mild	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	Mild	1 (8)	1 (8)	1 (9)	0 (0)	1 (8)	0 (0)	4 (6)
Dyspepsia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Gastrointestinal disorder	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	Moderate	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Vomiting	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
General disorders and administration site conditions	Any	11 (92)	0 (0)	9 (82)	0 (0)	11 (92)	11 (100)	42 (61)
Chills	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	Mild	7 (58)	0 (0)	4 (36)	0 (0)	5 (42)	1 (9)	17 (25)
	Moderate	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_5_1.sas (Page 5 of 60)

Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Influenza like illness	Mild	2 (17)	0 (0)	0 (0)	0 (0)	2 (17)	3 (27)	7 (10)
	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	4 (33)	7 (64)	12 (17)
Injection site discolouration	Mild	0 (0)	0 (0)	1 (9)	0 (0)	2 (17)	0 (0)	3 (4)
Injection site discomfort	Mild	3 (25)	0 (0)	2 (18)	0 (0)	1 (8)	1 (9)	7 (10)
Injection site erythema	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Injection site hypersensitivity	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Injection site pain	Mild	3 (25)	0 (0)	3 (27)	0 (0)	3 (25)	1 (9)	10 (14)
Injection site paraesthesia	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	Mild	3 (25)	0 (0)	4 (36)	0 (0)	7 (58)	4 (36)	18 (26)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	4 (36)	7 (10)
Pyrexia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	2 (3)
Infections and infestations	Any	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	0 (0)	2 (3)
Genital herpes	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Gingivitis	Moderate	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injury, poisoning and procedural complications	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Thermal burn	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Investigations	Any	1 (8)	0 (0)	1 (9)	0 (0)	1 (8)	1 (9)	4 (6)
Body temperature increased	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	2 (3)
Muscle strength abnormal	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	Any	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	3 (4)
Decreased appetite	Mild	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	3 (4)
Musculoskeletal and connective tissue disorders	Any	1 (8)	0 (0)	1 (9)	0 (0)	2 (17)	2 (18)	6 (9)
Arthralgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Back pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Muscle tightness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Musculoskeletal chest pain	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Myalgia	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myosclerosis	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Pain in extremity	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	Any	4 (33)	0 (0)	6 (55)	1 (9)	7 (58)	4 (36)	22 (32)
Dizziness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Head discomfort	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	Mild	2 (17)	0 (0)	3 (27)	0 (0)	6 (50)	1 (9)	12 (17)
	Moderate	2 (17)	0 (0)	2 (18)	0 (0)	1 (8)	2 (18)	7 (10)
	Severe	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Migraine	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Paraesthesia	Mild	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Tension headache	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Sleep disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Reproductive system and breast disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Dysmenorrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	1 (9)	3 (4)
Cough	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Dysphonia	Mild	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	0 (0)	2 (3)
Skin and subcutaneous tissue disorders	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Alopecia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Pruritus	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Blood and lymphatic system disorders	Any	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	Moderate	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Cardiac disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Cardiovascular disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Ear pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Vertigo	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	Any	1 (8)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (3)
Asthenopia	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	Severe	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	3 (4)
Abdominal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Abdominal pain upper	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Dry mouth	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
General disorders and administration site conditions	Any	7 (58)	0 (0)	11 (100)	0 (0)	11 (92)	11 (100)	40 (58)
Fatigue	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	Mild	0 (0)	0 (0)	2 (18)	0 (0)	3 (25)	2 (18)	7 (10)
	Moderate	5 (42)	0 (0)	4 (36)	0 (0)	7 (58)	6 (55)	22 (32)
	Severe	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (18)	3 (4)
Injection site discomfort	Mild	1 (8)	0 (0)	3 (27)	0 (0)	2 (17)	0 (0)	6 (9)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Injection site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Injection site pain	Mild	2 (17)	0 (0)	1 (9)	0 (0)	1 (8)	0 (0)	4 (6)
	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	Mild	1 (8)	0 (0)	4 (36)	0 (0)	2 (17)	5 (45)	12 (17)
	Moderate	3 (25)	0 (0)	2 (18)	0 (0)	6 (50)	6 (55)	17 (25)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Infections and infestations	Any	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	2 (18)	3 (4)
Conjunctivitis	Moderate	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Nasal herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nasopharyngitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Oral herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Tinea pedis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Investigations	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	Any	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	4 (6)
Decreased appetite	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	3 (4)
Musculoskeletal and connective tissue disorders	Any	1 (8)	0 (0)	1 (9)	1 (9)	1 (8)	2 (18)	6 (9)
Arthralgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Back pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Muscle tightness	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	Severe	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Myalgia	Moderate	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	2 (3)
Pain in extremity	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nervous system disorders	Any	4 (33)	0 (0)	5 (45)	1 (9)	3 (25)	3 (27)	16 (23)
Dizziness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	2 (3)
	Severe	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Headache	Mild	0 (0)	0 (0)	3 (27)	0 (0)	2 (17)	0 (0)	5 (7)
	Moderate	3 (25)	0 (0)	1 (9)	0 (0)	1 (8)	1 (9)	6 (9)
Presyncope	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Taste disorder	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Depression	Severe	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Hallucination	Severe	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Sleep disorder	Moderate	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bladder dysfunction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	1 (9)	2 (3)
Nasal congestion	Moderate	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Hot flush	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Blood and lymphatic system disorders	Any	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	Moderate	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Cardiac disorders	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	2 (3)
Cardiovascular disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Tachycardia	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Ear pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Vertigo	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	Any	1 (8)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (3)
Asthenopia	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	Severe	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	4 (36)	5 (7)
Abdominal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Abdominal pain upper	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Dry mouth	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysphagia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Vomiting	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
General disorders and administration site conditions	Any	7 (58)	0 (0)	11 (100)	0 (0)	11 (92)	11 (100)	40 (58)
Fatigue	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	Mild	0 (0)	0 (0)	2 (18)	0 (0)	3 (25)	2 (18)	7 (10)
	Moderate	5 (42)	0 (0)	4 (36)	0 (0)	7 (58)	6 (55)	22 (32)
	Severe	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (18)	3 (4)
Injection site discomfort	Mild	1 (8)	0 (0)	3 (27)	0 (0)	2 (17)	0 (0)	6 (9)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Injection site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Injection site pain	Mild	2 (17)	0 (0)	1 (9)	0 (0)	1 (8)	0 (0)	4 (6)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Injection site pain	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	Mild	1 (8)	0 (0)	4 (36)	0 (0)	2 (17)	5 (45)	12 (17)
	Moderate	3 (25)	0 (0)	2 (18)	0 (0)	6 (50)	6 (55)	17 (25)
Immune system disorders	Any	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Seasonal allergy	Moderate	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	Any	0 (0)	0 (0)	0 (0)	1 (9)	1 (8)	2 (18)	4 (6)
Conjunctivitis	Moderate	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Fungal infection	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nasal herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nasopharyngitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Oral herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Rhinitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Tinea pedis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Investigations	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Lymphocyte count increased	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	Any	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	4 (6)
Decreased appetite	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	3 (4)
Musculoskeletal and connective tissue disorders	Any	1 (8)	0 (0)	1 (9)	1 (9)	2 (17)	2 (18)	7 (10)
Arthralgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	2 (3)
Back pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Muscle tightness	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	Severe	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Myalgia	Moderate	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	2 (3)
Pain in extremity	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nervous system disorders	Any	5 (42)	0 (0)	7 (64)	2 (18)	4 (33)	3 (27)	21 (30)
Cervicobrachial syndrome	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Dizziness	Moderate	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
	Severe	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Headache	Mild	0 (0)	0 (0)	2 (18)	0 (0)	2 (17)	0 (0)	4 (6)
	Moderate	4 (33)	0 (0)	4 (36)	1 (9)	2 (17)	1 (9)	12 (17)
Presyncope	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Taste disorder	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tension headache	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Depression	Severe	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Hallucination	Severe	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Sleep disorder	Moderate	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bladder dysfunction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	1 (9)	3 (4)
Nasal congestion	Moderate	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Rhinitis allergic	Moderate	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Pityriasis rosea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Hot flush	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Blood and lymphatic system disorders	Any	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	Moderate	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Cardiac disorders	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	2 (3)
Cardiovascular disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Tachycardia	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Ear pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Vertigo	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	Any	1 (8)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (3)
Asthenopia	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	Severe	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	Any	1 (8)	1 (8)	1 (9)	2 (18)	1 (8)	4 (36)	10 (14)
Abdominal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Abdominal pain lower	Mild	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	Mild	1 (8)	1 (8)	1 (9)	0 (0)	1 (8)	1 (9)	5 (7)
Dry mouth	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspepsia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Dysphagia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Gastrointestinal disorder	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	Moderate	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Vomiting	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
General disorders and administration site conditions	Any	11 (92)	0 (0)	11 (100)	0 (0)	11 (92)	11 (100)	44 (64)
Chills	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	Mild	7 (58)	0 (0)	4 (36)	0 (0)	5 (42)	1 (9)	17 (25)
	Moderate	1 (8)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	2 (3)
Influenza like illness	Mild	0 (0)	0 (0)	2 (18)	0 (0)	3 (25)	2 (18)	7 (10)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Influenza like illness	Moderate	5 (42)	0 (0)	4 (36)	0 (0)	7 (58)	6 (55)	22 (32)
	Severe	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	2 (18)	3 (4)
Injection site discolouration	Mild	0 (0)	0 (0)	1 (9)	0 (0)	2 (17)	0 (0)	3 (4)
Injection site discomfort	Mild	3 (25)	0 (0)	5 (45)	0 (0)	2 (17)	1 (9)	11 (16)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Injection site erythema	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	2 (3)
Injection site hypersensitivity	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Injection site pain	Mild	3 (25)	0 (0)	4 (36)	0 (0)	3 (25)	1 (9)	11 (16)
	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site paraesthesia	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	Mild	1 (8)	0 (0)	5 (45)	0 (0)	3 (25)	4 (36)	13 (19)
	Moderate	3 (25)	0 (0)	2 (18)	0 (0)	7 (58)	7 (64)	19 (28)
Pyrexia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Immune system disorders	Any	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Seasonal allergy	Moderate	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	Any	0 (0)	0 (0)	2 (18)	1 (9)	1 (8)	2 (18)	6 (9)
Conjunctivitis	Moderate	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Fungal infection	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Genital herpes	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Gingivitis	Moderate	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nasopharyngitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Oral herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Rhinitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Tinea pedis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Injury, poisoning and procedural complications	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Thermal burn	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Investigations	Any	2 (17)	0 (0)	1 (9)	0 (0)	1 (8)	1 (9)	5 (7)
Body temperature increased	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	2 (3)
Lymphocyte count increased	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle strength abnormal	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	Any	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	3 (27)	6 (9)
Decreased appetite	Mild	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	3 (4)
	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)	3 (4)
Musculoskeletal and connective tissue disorders	Any	1 (8)	0 (0)	2 (18)	1 (9)	3 (25)	3 (27)	10 (14)
Arthralgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (9)	2 (3)
Back pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
Muscle tightness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Musculoskeletal chest pain	Severe	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Myalgia	Moderate	1 (8)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	3 (4)
Myosclerosis	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Pain in extremity	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Nervous system disorders	Any	6 (50)	0 (0)	8 (73)	2 (18)	8 (67)	5 (45)	29 (42)
Cervicobrachial syndrome	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	2 (18)	3 (4)
	Moderate	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
	Severe	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Head discomfort	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	Mild	1 (8)	0 (0)	4 (36)	0 (0)	5 (42)	1 (9)	11 (16)
	Moderate	4 (33)	0 (0)	4 (36)	0 (0)	3 (25)	3 (27)	14 (20)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Headache	Severe	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Migraine	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Paraesthesia	Mild	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Presyncope	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Taste disorder	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tension headache	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Depression	Severe	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Hallucination	Severe	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Sleep disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Moderate	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Bladder dysfunction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Pollakiuria	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Reproductive system and breast disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Dysmenorrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	0 (0)	2 (18)	2 (18)	0 (0)	2 (18)	6 (9)
Cough	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)	1 (1)
Dysphonia	Mild	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Nasal congestion	Moderate	0 (0)	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	1 (9)	1 (9)	0 (0)	1 (9)	3 (4)
Rhinitis allergic	Moderate	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	Any	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (3)
Alopecia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pityriasis rosea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts						
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	50 µg (N=11) n (%)	Total (N=69) n (%)
Pruritus	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	2 (3)
Hot flush	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (9)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 7 after prime

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Gastrointestinal disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	8 (8)
Abdominal pain lower	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Gastrointestinal disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	Any	0 (0)	0 (0)	0 (0)	0 (0)	41 (39)
Chills	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	Mild	0 (0)	0 (0)	0 (0)	0 (0)	17 (16)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	11 (11)
Injection site discolouration	Mild	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 7 after prime

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Injection site discomfort	Mild	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
Injection site erythema	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypersensitivity	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	9 (9)
Injection site reaction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	17 (16)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
Pyrexia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Infections and infestations	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	Any	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Body temperature increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Metabolism and nutrition disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 7 after prime

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Decreased appetite	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Musculoskeletal and connective tissue disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Arthralgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	22 (21)
Dizziness	Mild	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Head discomfort	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	Mild	0 (0)	0 (0)	0 (0)	0 (0)	12 (12)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
Paraesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Sleep disorder	Mild	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Renal and urinary disorders	Any	0 (0)	0 (0)	3 (25)	3 (9)	3 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 7 after prime

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Pollakiuria	Mild	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	0 (0)	2 (17)	2 (6)	5 (5)
Cough	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysphonia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)
Skin and subcutaneous tissue disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Alopecia	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pruritus	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Ear pain	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Gastrointestinal disorders	Any	0 (0)	0 (0)	2 (17)	2 (6)	9 (9)
Abdominal pain lower	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Dyspepsia	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Gastrointestinal disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	Any	0 (0)	0 (0)	0 (0)	0 (0)	42 (40)
Chills	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	Mild	0 (0)	0 (0)	0 (0)	0 (0)	17 (16)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Influenza like illness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	12 (12)
Injection site discolouration	Mild	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site discomfort	Mild	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
Injection site erythema	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site hypersensitivity	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	10 (10)
Injection site paraesthesia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	18 (17)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
Pyrexia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Infections and infestations	Any	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Genital herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Gingivitis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Injury, poisoning and procedural complications	Any	0 (0)	1 (9)	0 (0)	1 (3)	1 (1)
Thermal burn	Mild	0 (0)	1 (9)	0 (0)	1 (3)	1 (1)
Investigations	Any	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Body temperature increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Muscle strength abnormal	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Decreased appetite	Mild	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Musculoskeletal and connective tissue disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
Arthralgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Back pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle tightness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Musculoskeletal chest pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myalgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myosclerosis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	Any	1 (8)	0 (0)	1 (8)	2 (6)	24 (23)
Dizziness	Mild	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Head discomfort	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	Mild	0 (0)	0 (0)	0 (0)	0 (0)	12 (12)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Migraine	Severe	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Paraesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tension headache	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Psychiatric disorders	Any	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Sleep disorder	Mild	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Renal and urinary disorders	Any	0 (0)	0 (0)	3 (25)	3 (9)	3 (3)
Pollakiuria	Mild	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Reproductive system and breast disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysmenorrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	Any	2 (17)	0 (0)	2 (17)	4 (11)	7 (7)
Cough	Mild	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
	Moderate	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Dysphonia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)
Skin and subcutaneous tissue disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Alopecia	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Pruritus	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Blood and lymphatic system disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiovascular disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Ear pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vertigo	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Asthenopia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
Abdominal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Dry mouth	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	Any	0 (0)	0 (0)	0 (0)	0 (0)	40 (38)
Fatigue	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	22 (21)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site discomfort	Mild	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	12 (12)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	17 (16)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Infections and infestations	Any	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
Conjunctivitis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Oral herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tinea pedis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphocyte count increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Decreased appetite	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Musculoskeletal and connective tissue disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
Arthralgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Back pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Muscle tightness	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myalgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Pain in extremity	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	16 (15)
Dizziness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	Mild	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
Presyncope	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Taste disorder	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Depression	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Boost up to Day 7 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Hallucination	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Bladder dysfunction	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Nasal congestion	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Blood and lymphatic system disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Cardiovascular disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tachycardia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Ear pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vertigo	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Asthenopia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	6 (6)
Abdominal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Abdominal pain upper	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dry mouth	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysphagia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	Any	0 (0)	0 (0)	0 (0)	0 (0)	40 (38)
Fatigue	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	22 (21)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site discomfort	Mild	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Injection site pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	12 (12)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	17 (16)
Immune system disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Seasonal allergy	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	Any	0 (0)	0 (0)	1 (8)	1 (3)	5 (5)
Conjunctivitis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fungal infection	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Oral herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tinea pedis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Lymphocyte count increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Decreased appetite	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Musculoskeletal and connective tissue disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
Arthralgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Back pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle tightness	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myalgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Pain in extremity	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	21 (20)
Cervicobrachial syndrome	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Dizziness	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	Mild	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	12 (12)
Presyncope	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Taste disorder	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tension headache	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Depression	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Bladder dysfunction	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Boost up to Day 28 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Nasal congestion	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis allergic	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pityriasis rosea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Blood and lymphatic system disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Cardiovascular disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tachycardia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Ear pain	Mild	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Vertigo	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Eye disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Asthenopia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye irritation	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Photophobia	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	Any	0 (0)	0 (0)	2 (17)	2 (6)	12 (12)
Abdominal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Abdominal pain lower	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain upper	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
Dry mouth	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspepsia	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Dysphagia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorder	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingival pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vomiting	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	Any	0 (0)	0 (0)	0 (0)	0 (0)	44 (42)
Chills	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	Mild	0 (0)	0 (0)	0 (0)	0 (0)	17 (16)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Influenza like illness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Influenza like illness	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	22 (21)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site discolouration	Mild	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site discomfort	Mild	0 (0)	0 (0)	0 (0)	0 (0)	11 (11)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site erythema	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Injection site hypersensitivity	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	11 (11)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site paraesthesia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	13 (13)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	19 (18)
Pyrexia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Immune system disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Seasonal allergy	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	Any	0 (0)	0 (0)	2 (17)	2 (6)	8 (8)
Conjunctivitis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fungal infection	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Genital herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gingivitis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	Mild	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Oral herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tinea pedis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	Any	0 (0)	1 (9)	0 (0)	1 (3)	1 (1)
Thermal burn	Mild	0 (0)	1 (9)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Investigations	Any	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
Body temperature increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
C-reactive protein increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Lymphocyte count increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle strength abnormal	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Metabolism and nutrition disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
Decreased appetite	Mild	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Musculoskeletal and connective tissue disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	10 (10)
Arthralgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Back pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Muscle tightness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal chest pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Musculoskeletal chest pain	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Myalgia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Myosclerosis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Neck pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pain in extremity	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	Any	1 (8)	0 (0)	1 (8)	2 (6)	31 (30)
Cervicobrachial syndrome	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dizziness	Mild	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Head discomfort	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Headache	Mild	0 (0)	0 (0)	0 (0)	0 (0)	11 (11)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	14 (13)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_5_1.sas (Page 57 of 60)

Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Headache	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Migraine	Severe	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Paraesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Presyncope	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Taste disorder	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tension headache	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)
Depression	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hallucination	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sleep disorder	Mild	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	Any	0 (0)	0 (0)	3 (25)	3 (9)	3 (3)
Bladder dysfunction	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_5_1.sas (Page 58 of 60)

Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Pollakiuria	Mild	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Reproductive system and breast disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysmenorrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	Any	2 (17)	0 (0)	2 (17)	4 (11)	10 (10)
Cough	Mild	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
	Moderate	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Dysphonia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasal congestion	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	2 (17)	2 (6)	5 (5)
Rhinitis allergic	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Alopecia	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Pityriasis rosea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_5_1.sas (Page 59 of 60)

Table 14.3.1-3.5.1-1: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b1

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=11) n (%)	30 µg (N=12) n (%)	Total (N=35) n (%)	Total (N=104) n (%)
Pruritus	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Hot flush	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_5_1.sas (Page 60 of 60)

Listing 14.3.1-3.7.1-1: Listing of serious adverse events - BNT162b1

Safety set

Subject number/ Dose group	Reported term/ Coded term	Start date/ time	End date/ time	Duration [h]/ Days since last dose	Action taken/ Concomitant or additional treatment given	Relationship/ Outcome	Grade/ Serious-ness	TEAE/ TEAESI	Epi-/pandemic related indicator/ Dose limiting toxicity
20242 20 µg Older	syncope Syncope	20SEP2020 3:05	24SEP2020	- 12	Drug Withdrawn No	Not Related Recovered/Resolved	Severe Yes	Yes No	No No

Adverse events are coded using MedDRA version MedDRA 23.0.
TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.

Program: Tsaf_AE_71.sas (Page 1 of 1)

14.3.2 Further safety endpoints
14.3.2-1 Compliance

Table 14.3.2-1.1-1: IMP compliance - BNT162b1

Safety set

	Younger dose ranging cohorts							
	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Subjects receiving first immunization	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
Subjects receiving boost immunization	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	0 (0)	69 (82)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_IMP_1_1.sas (Page 1 of 2)

Table 14.3.2-1.1-1: IMP compliance - BNT162b1

Safety set

	Older dose ranging cohorts				
	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Subjects receiving first immunization	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
Subjects receiving boost immunization	12 (100)	11 (92)	12 (100)	35 (97)	104 (87)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_IMP_1_1.sas (Page 2 of 2)

Table 14.3.2-1.2-1: Diary compliance local reactions - BNT162b1

Safety set

		Younger dose ranging cohorts							
	Day after immunization	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
After prime	0	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	1	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	2	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	3	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	4	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	5	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	6	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	7	2 (17)	6 (50)	11 (92)	4 (33)	2 (17)	0 (0)	3 (25)	28 (33)
After boost	0	11 (92)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	N/A	68 (81)
	1	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	N/A	69 (82)
	2	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	N/A	69 (82)
	3	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	N/A	69 (82)
	4	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	N/A	69 (82)
	5	11 (92)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	N/A	68 (81)
	6	6 (50)	7 (58)	11 (92)	11 (92)	11 (92)	8 (67)	N/A	54 (64)
	7	0 (0)	2 (17)	9 (75)	6 (50)	7 (58)	0 (0)	N/A	24 (29)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with diary compliance on local reactions on the specified day.

Program: Tfsaf_diary_1_2.sas (Page 1 of 2)

Table 14.3.2-1.2-1: Diary compliance local reactions - BNT162b1

Safety set

		Older dose ranging cohorts				
	Day after immunization	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
After prime	0	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)
	1	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	2	11 (92)	12 (100)	12 (100)	35 (97)	119 (99)
	3	11 (92)	12 (100)	12 (100)	35 (97)	119 (99)
	4	11 (92)	12 (100)	12 (100)	35 (97)	119 (99)
	5	11 (92)	12 (100)	12 (100)	35 (97)	119 (99)
	6	11 (92)	12 (100)	12 (100)	35 (97)	119 (99)
	7	1 (8)	8 (67)	1 (8)	10 (28)	38 (32)
After boost	0	12 (100)	11 (92)	12 (100)	35 (97)	103 (86)
	1	12 (100)	11 (92)	12 (100)	35 (97)	104 (87)
	2	12 (100)	11 (92)	12 (100)	35 (97)	104 (87)
	3	12 (100)	11 (92)	12 (100)	35 (97)	104 (87)
	4	12 (100)	11 (92)	12 (100)	35 (97)	104 (87)
	5	12 (100)	11 (92)	12 (100)	35 (97)	103 (86)
	6	12 (100)	10 (83)	10 (83)	32 (89)	86 (72)
	7	1 (8)	8 (67)	1 (8)	10 (28)	34 (28)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with diary compliance on local reactions on the specified day.

Program: Tfsaf_diary_1_2.sas (Page 2 of 2)

Table 14.3.2-1.3-1: Diary compliance systemic reactions - BNT162b1

Safety set

		Younger dose ranging cohorts							
	Day after immunization	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
After prime	0	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	1	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	2	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	3	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	4	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	5	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	6	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	7	2 (17)	7 (58)	11 (92)	4 (33)	2 (17)	0 (0)	2 (17)	28 (33)
After boost	0	11 (92)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	N/A	68 (81)
	1	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	N/A	69 (82)
	2	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	N/A	69 (82)
	3	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	N/A	69 (82)
	4	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	N/A	69 (82)
	5	11 (92)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	N/A	68 (81)
	6	6 (50)	7 (58)	11 (92)	11 (92)	11 (92)	8 (67)	N/A	54 (64)
	7	0 (0)	1 (8)	9 (75)	6 (50)	6 (50)	0 (0)	N/A	22 (26)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with diary compliance on systemic reactions on the specified day.

Program: Tfsaf_diary_1_2.sas (Page 1 of 2)

Table 14.3.2-1.3-1: Diary compliance systemic reactions - BNT162b1

Safety set

		Older dose ranging cohorts				
	Day after immunization	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
After prime	0	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)
	1	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	2	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	3	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	4	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	5	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	6	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	7	1 (8)	8 (67)	0 (0)	9 (25)	37 (31)
After boost	0	12 (100)	11 (92)	12 (100)	35 (97)	103 (86)
	1	12 (100)	11 (92)	12 (100)	35 (97)	104 (87)
	2	12 (100)	11 (92)	12 (100)	35 (97)	104 (87)
	3	12 (100)	11 (92)	12 (100)	35 (97)	104 (87)
	4	12 (100)	11 (92)	12 (100)	35 (97)	104 (87)
	5	12 (100)	11 (92)	12 (100)	35 (97)	103 (86)
	6	12 (100)	11 (92)	10 (83)	33 (92)	87 (73)
	7	1 (8)	8 (67)	1 (8)	10 (28)	32 (27)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with diary compliance on systemic reactions on the specified day.

Program: Tfsaf_diary_1_2.sas (Page 2 of 2)

14.3.2-2 Laboratory
14.3.2-2.1 Descriptive statistics

Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Basophils (Blood) [10^9/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.038 (0.026)	0.043 (0.021)	0.063 (0.030)	0.054 (0.029)	0.031 (0.011)	0.054 (0.020)	0.038 (0.013)	0.046 (0.024)
		Min	0.01	0.02	0.03	0.02	0.01	0.02	0.02	0.01
		Median	0.035	0.040	0.060	0.050	0.030	0.055	0.040	0.040
		Max	0.09	0.09	0.13	0.09	0.05	0.09	0.07	0.13
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.038 (0.025)	0.034 (0.017)	0.062 (0.029)	0.052 (0.022)	0.033 (0.012)	0.053 (0.021)	0.039 (0.014)	0.044 (0.022)
		Min	0.01	0.02	0.02	0.02	0.02	0.02	0.02	0.01
		Median	0.030	0.030	0.060	0.045	0.030	0.055	0.040	0.040
		Max	0.10	0.07	0.13	0.09	0.06	0.08	0.06	0.13
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.033 (0.025)	0.040 (0.016)	0.051 (0.027)	0.041 (0.017)	0.019 (0.008)	0.036 (0.017)	0.027 (0.011)	0.035 (0.020)
		Min	0.01	0.01	0.02	0.02	0.01	0.02	0.01	0.01
		Median	0.030	0.045	0.050	0.045	0.020	0.030	0.030	0.030
		Max	0.08	0.06	0.09	0.07	0.04	0.08	0.04	0.09

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

Program: Tfsaf_LB_2_1.sas (Page 1 of 74)

Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Basophils (Blood) [10^9/L]	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.036 (0.024)	0.041 (0.017)	0.048 (0.022)	0.038 (0.016)	0.022 (0.007)	0.038 (0.011)	0.023 (0.008)	0.035 (0.018)
		Min	0.01	0.02	0.02	0.02	0.01	0.02	0.01	0.01
		Median	0.030	0.035	0.045	0.035	0.020	0.040	0.020	0.030
		Max	0.09	0.07	0.09	0.08	0.03	0.06	0.04	0.09
	Day 29	n	12	12	11	11	12	9	12	79
		Mean (SD)	0.037 (0.023)	0.043 (0.014)	0.055 (0.027)	0.037 (0.017)	0.032 (0.012)	0.042 (0.011)	0.033 (0.010)	0.039 (0.018)
		Min	0.01	0.02	0.02	0.02	0.02	0.03	0.02	0.01
		Median	0.030	0.045	0.050	0.030	0.030	0.040	0.030	0.040
		Max	0.09	0.07	0.11	0.07	0.06	0.06	0.05	0.11
	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	0.035 (0.021)	0.043 (0.020)	0.061 (0.027)	0.050 (0.027)	0.036 (0.015)	0.048 (0.017)	0.045 (0.019)	0.045 (0.022)
		Min	0.01	0.02	0.02	0.02	0.02	0.02	0.02	0.01
		Median	0.030	0.040	0.060	0.040	0.030	0.045	0.040	0.040
		Max	0.08	0.08	0.11	0.11	0.07	0.07	0.08	0.11

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

Program: Tfsaf_LB_2_1.sas (Page 2 of 74)

Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Basophils (Blood Smear) [10^9/L]	Day 1	n	0	0	0	0	0	0	0	0
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
		Min	-	-	-	-	-	-	-	-
		Median	-	-	-	-	-	-	-	-
		Max	-	-	-	-	-	-	-	-
	Day 29	n	0	0	0	0	0	2	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	0.045 (-)	- (-)	0.045 (-)
		Min	-	-	-	-	-	0.00	-	0.00
		Median	-	-	-	-	-	0.045	-	0.045
		Max	-	-	-	-	-	0.09	-	0.09
Basophils/Leukocytes (Blood) [%]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.68 (0.44)	0.68 (0.31)	0.92 (0.34)	0.89 (0.46)	0.50 (0.21)	0.91 (0.27)	0.70 (0.26)	0.75 (0.36)
		Min	0.1	0.3	0.4	0.3	0.2	0.4	0.3	0.1
		Median	0.65	0.60	0.95	0.90	0.45	0.90	0.70	0.70
		Max	1.6	1.4	1.5	1.8	0.8	1.3	1.3	1.8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Basophils/Leukocytes (Blood) [%]	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.70 (0.41)	0.57 (0.21)	1.02 (0.39)	0.93 (0.44)	0.61 (0.25)	0.87 (0.33)	0.72 (0.26)	0.77 (0.36)
		Min	0.3	0.3	0.3	0.3	0.4	0.4	0.3	0.3
		Median	0.65	0.50	1.00	0.95	0.50	0.90	0.70	0.70
		Max	1.7	1.0	1.8	1.8	1.2	1.5	1.2	1.8
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.60 (0.39)	0.67 (0.26)	0.85 (0.36)	0.70 (0.29)	0.38 (0.19)	0.58 (0.14)	0.44 (0.15)	0.60 (0.30)
		Min	0.1	0.3	0.4	0.3	0.2	0.4	0.1	0.1
		Median	0.60	0.60	0.75	0.75	0.30	0.50	0.50	0.50
		Max	1.3	1.1	1.7	1.2	0.9	0.8	0.6	1.7
	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.70 (0.39)	0.74 (0.27)	0.85 (0.31)	0.70 (0.30)	0.46 (0.20)	0.73 (0.22)	0.47 (0.12)	0.66 (0.30)
		Min	0.3	0.5	0.4	0.3	0.2	0.4	0.2	0.2
		Median	0.60	0.70	0.90	0.70	0.40	0.70	0.50	0.60
		Max	1.5	1.4	1.2	1.5	0.8	1.1	0.7	1.5

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Basophils/Leukocytes (Blood) [%]	Day 29	n	12	12	11	11	12	9	12	79
		Mean (SD)	0.67 (0.36)	0.69 (0.21)	0.85 (0.40)	0.70 (0.26)	0.59 (0.25)	0.76 (0.32)	0.62 (0.19)	0.69 (0.29)
		Min	0.3	0.4	0.4	0.3	0.3	0.3	0.3	0.3
		Median	0.55	0.65	0.80	0.70	0.50	0.70	0.60	0.60
		Max	1.5	1.1	1.7	1.1	1.1	1.4	0.9	1.7
	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	0.68 (0.38)	0.69 (0.30)	0.96 (0.37)	0.92 (0.38)	0.66 (0.22)	0.84 (0.28)	0.84 (0.29)	0.80 (0.33)
		Min	0.2	0.3	0.3	0.5	0.4	0.4	0.4	0.2
		Median	0.60	0.60	1.10	0.80	0.60	0.90	0.90	0.75
		Max	1.4	1.3	1.6	1.6	1.0	1.3	1.3	1.6
Basophils/Leukocytes (Blood Smear) [%]	Day 1	n	0	0	0	0	0	0	0	0
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
		Min	-	-	-	-	-	-	-	-
		Median	-	-	-	-	-	-	-	-
		Max	-	-	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

Program: Tfsaf_LB_2_1.sas (Page 5 of 74)

Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Basophils/Leukocytes (Blood Smear) [%]	Day 29	n	0	0	0	0	0	2	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	1.0 (-)	- (-)	1.0 (-)
		Min	-	-	-	-	-	0	-	0
		Median	-	-	-	-	-	1.0	-	1.0
		Max	-	-	-	-	-	2	-	2
Eosinophils (Blood) [10^9/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.156 (0.085)	0.178 (0.155)	0.220 (0.134)	0.217 (0.125)	0.172 (0.110)	0.185 (0.114)	0.126 (0.110)	0.179 (0.120)
		Min	0.03	0.04	0.05	0.10	0.04	0.07	0.04	0.03
		Median	0.165	0.145	0.180	0.175	0.150	0.150	0.075	0.140
		Max	0.29	0.58	0.44	0.44	0.37	0.41	0.36	0.58
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.174 (0.112)	0.151 (0.111)	0.198 (0.132)	0.190 (0.102)	0.158 (0.092)	0.182 (0.120)	0.130 (0.105)	0.169 (0.109)
		Min	0.04	0.02	0.05	0.10	0.05	0.05	0.04	0.02
		Median	0.130	0.135	0.145	0.150	0.145	0.135	0.090	0.140
		Max	0.39	0.34	0.51	0.45	0.33	0.42	0.40	0.51

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Eosinophils (Blood) [10^9/L]	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.168 (0.095)	0.159 (0.088)	0.184 (0.144)	0.136 (0.066)	0.088 (0.064)	0.093 (0.113)	0.058 (0.063)	0.127 (0.101)
		Min	0.06	0.04	0.02	0.05	0.02	0.02	0.01	0.01
		Median	0.130	0.145	0.135	0.130	0.075	0.050	0.030	0.110
		Max	0.34	0.30	0.57	0.27	0.22	0.38	0.22	0.57
	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.163 (0.100)	0.181 (0.134)	0.173 (0.116)	0.195 (0.087)	0.161 (0.098)	0.184 (0.127)	0.124 (0.097)	0.169 (0.108)
		Min	0.06	0.04	0.03	0.06	0.03	0.04	0.04	0.03
		Median	0.150	0.155	0.125	0.185	0.155	0.115	0.080	0.140
		Max	0.35	0.51	0.42	0.32	0.38	0.40	0.35	0.51
	Day 29	n	12	12	11	11	12	9	12	79
		Mean (SD)	0.206 (0.144)	0.181 (0.118)	0.230 (0.089)	0.166 (0.086)	0.256 (0.161)	0.233 (0.128)	0.121 (0.082)	0.198 (0.122)
		Min	0.04	0.03	0.14	0.06	0.04	0.08	0.05	0.03
		Median	0.180	0.185	0.200	0.150	0.255	0.220	0.085	0.180
		Max	0.53	0.40	0.37	0.34	0.51	0.45	0.32	0.53

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Eosinophils (Blood) [10^9/L]	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	0.205 (0.114)	0.159 (0.111)	0.229 (0.097)	0.232 (0.227)	0.288 (0.284)	0.196 (0.107)	0.135 (0.090)	0.206 (0.165)
		Min	0.08	0.02	0.09	0.05	0.04	0.07	0.06	0.02
		Median	0.180	0.145	0.230	0.160	0.205	0.200	0.095	0.170
		Max	0.40	0.38	0.37	0.87	0.95	0.41	0.35	0.95
Eosinophils (Blood Smear) [10^9/L]	Day 1	n	0	0	0	0	0	0	0	0
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
		Min	-	-	-	-	-	-	-	-
		Median	-	-	-	-	-	-	-	-
		Max	-	-	-	-	-	-	-	-
	Day 29	n	0	0	0	0	0	2	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	0.125 (-)	- (-)	0.125 (-)
		Min	-	-	-	-	-	0.12	-	0.12
		Median	-	-	-	-	-	0.125	-	0.125
		Max	-	-	-	-	-	0.13	-	0.13

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Eosinophils/Leukocytes (Blood) [%]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	2.91 (2.01)	2.65 (2.09)	3.19 (1.97)	3.43 (1.57)	2.85 (1.79)	3.12 (1.88)	2.26 (1.92)	2.91 (1.86)
		Min	0.5	0.4	1.1	1.8	0.4	1.0	0.7	0.4
		Median	2.70	2.25	2.50	2.70	2.85	2.60	1.35	2.35
		Max	7.7	8.0	7.0	5.9	6.0	6.8	6.5	8.0
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	3.33 (2.14)	2.61 (1.99)	3.22 (1.98)	3.26 (1.47)	2.98 (1.86)	2.87 (1.75)	2.42 (2.10)	2.95 (1.87)
		Min	0.6	0.3	1.3	1.5	0.7	1.2	0.5	0.3
		Median	2.90	2.25	2.70	3.00	2.95	2.15	1.50	2.45
		Max	7.5	7.6	7.5	6.8	6.5	6.4	7.8	7.8
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	3.19 (1.95)	2.43 (0.94)	3.03 (2.01)	2.23 (1.11)	1.69 (1.10)	1.33 (1.27)	0.98 (1.12)	2.13 (1.57)
		Min	1.2	0.9	0.7	0.9	0.3	0.4	0.1	0.1
		Median	2.75	2.45	2.30	1.95	1.65	0.75	0.50	1.90
		Max	8.2	3.8	7.8	4.4	3.9	4.0	4.0	8.2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Eosinophils/Leukocytes (Blood) [%]	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	3.27 (2.03)	3.12 (1.93)	3.16 (2.19)	3.49 (1.50)	3.23 (1.88)	3.43 (2.23)	2.40 (1.59)	3.16 (1.88)
		Min	1.4	0.9	1.0	1.3	0.7	0.9	1.0	0.7
		Median	2.85	2.45	2.30	3.20	3.40	2.40	1.90	2.55
		Max	8.2	7.2	8.1	6.3	7.1	7.7	6.2	8.2
	Day 29	n	12	12	11	11	12	9	12	79
		Mean (SD)	3.70 (2.11)	2.85 (1.67)	3.79 (1.92)	3.05 (1.27)	4.47 (2.46)	4.00 (2.12)	2.21 (1.23)	3.42 (1.94)
		Min	0.6	0.6	1.3	1.2	0.7	0.9	1.0	0.6
		Median	3.55	2.60	3.30	2.70	4.65	3.70	1.75	3.10
		Max	8.0	5.6	7.0	5.1	9.3	8.2	5.0	9.3
	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	4.13 (2.67)	2.50 (1.43)	3.70 (1.62)	3.98 (3.10)	4.84 (4.02)	3.39 (1.91)	2.47 (1.32)	3.56 (2.53)
		Min	1.4	0.5	1.6	1.2	0.7	1.1	1.1	0.5
		Median	3.60	2.35	4.00	2.85	4.70	3.05	2.15	2.80
		Max	10.1	5.3	5.8	11.7	15.3	8.0	5.8	15.3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Eosinophils/Leukocytes (Blood Smear) [%]	Day 1	n	0	0	0	0	0	0	0	0
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
		Min	-	-	-	-	-	-	-	-
		Median	-	-	-	-	-	-	-	-
		Max	-	-	-	-	-	-	-	-
	Day 29	n	0	0	0	0	0	2	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	3.0 (-)	- (-)	3.0 (-)
		Min	-	-	-	-	-	3	-	3
		Median	-	-	-	-	-	3.0	-	3.0
		Max	-	-	-	-	-	3	-	3
Erythrocytes (Blood) [10^{12}/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	4.68 (0.53)	4.96 (0.39)	4.59 (0.43)	4.83 (0.47)	4.72 (0.32)	4.74 (0.45)	4.91 (0.38)	4.78 (0.43)
		Min	4.0	4.2	3.8	4.1	4.1	4.1	4.2	3.8
		Median	4.45	4.90	4.60	4.75	4.75	4.60	5.05	4.75
		Max	5.7	5.6	5.2	5.9	5.2	5.5	5.5	5.9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Erythrocytes (Blood) [10^{12}/L]	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	4.62 (0.47)	4.79 (0.32)	4.30 (0.47)	4.78 (0.47)	4.67 (0.37)	4.75 (0.46)	4.67 (0.33)	4.65 (0.43)
		Min	4.0	4.2	3.5	4.1	4.1	4.1	4.2	3.5
		Median	4.55	4.75	4.20	4.80	4.70	4.65	4.70	4.70
		Max	5.5	5.4	5.1	5.9	5.2	5.6	5.4	5.9
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	4.53 (0.50)	4.75 (0.45)	4.25 (0.42)	4.65 (0.36)	4.63 (0.38)	4.52 (0.49)	4.49 (0.34)	4.55 (0.43)
		Min	4.0	3.7	3.6	4.1	4.0	3.8	3.9	3.6
		Median	4.35	4.80	4.20	4.50	4.70	4.50	4.50	4.50
		Max	5.5	5.4	4.9	5.4	5.2	5.4	5.1	5.5
	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	4.62 (0.52)	4.75 (0.41)	4.20 (0.51)	4.70 (0.50)	4.59 (0.37)	4.44 (0.44)	4.63 (0.36)	4.56 (0.46)
		Min	4.1	4.0	3.6	4.1	4.1	3.8	4.1	3.6
		Median	4.45	4.70	4.20	4.65	4.70	4.45	4.65	4.50
		Max	5.5	5.6	5.1	5.9	5.2	5.3	5.4	5.9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Erythrocytes (Blood) [10^{12}/L]	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	4.65 (0.40)	4.77 (0.43)	4.31 (0.49)	4.58 (0.49)	4.62 (0.33)	4.49 (0.54)	4.61 (0.44)	4.58 (0.45)
		Min	4.2	4.1	3.6	3.7	4.1	3.7	4.0	3.6
		Median	4.45	4.70	4.30	4.50	4.60	4.40	4.55	4.50
		Max	5.3	5.9	5.3	5.8	5.2	5.5	5.5	5.9
	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	4.45 (0.48)	4.74 (0.44)	4.38 (0.45)	4.57 (0.39)	4.59 (0.36)	4.52 (0.42)	4.69 (0.38)	4.57 (0.42)
		Min	3.9	3.8	3.6	4.1	4.0	3.8	4.3	3.6
		Median	4.30	4.80	4.40	4.50	4.65	4.55	4.65	4.60
		Max	5.5	5.6	5.1	5.6	5.1	5.3	5.5	5.6
Hematocrit [L/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.428 (0.037)	0.438 (0.034)	0.416 (0.032)	0.442 (0.026)	0.434 (0.026)	0.429 (0.036)	0.435 (0.026)	0.432 (0.031)
		Min	0.37	0.38	0.37	0.40	0.39	0.37	0.39	0.37
		Median	0.415	0.430	0.415	0.440	0.430	0.420	0.450	0.430
		Max	0.48	0.50	0.47	0.48	0.48	0.49	0.46	0.50

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Hematocrit [L/L]	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.418 (0.031)	0.430 (0.033)	0.413 (0.040)	0.436 (0.024)	0.428 (0.029)	0.432 (0.040)	0.418 (0.021)	0.425 (0.032)
		Min	0.36	0.38	0.36	0.40	0.36	0.37	0.39	0.36
		Median	0.420	0.430	0.410	0.430	0.430	0.430	0.415	0.430
		Max	0.47	0.48	0.49	0.47	0.47	0.50	0.46	0.50
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.403 (0.036)	0.425 (0.045)	0.403 (0.036)	0.423 (0.018)	0.419 (0.028)	0.408 (0.039)	0.413 (0.032)	0.413 (0.034)
		Min	0.36	0.34	0.35	0.39	0.37	0.36	0.36	0.34
		Median	0.390	0.435	0.390	0.425	0.420	0.400	0.420	0.410
		Max	0.47	0.48	0.46	0.45	0.45	0.48	0.46	0.48
	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.409 (0.037)	0.425 (0.039)	0.380 (0.040)	0.432 (0.029)	0.415 (0.030)	0.403 (0.037)	0.408 (0.026)	0.410 (0.037)
		Min	0.36	0.36	0.33	0.39	0.37	0.34	0.37	0.33
		Median	0.400	0.425	0.370	0.435	0.420	0.400	0.405	0.410
		Max	0.48	0.48	0.45	0.47	0.47	0.48	0.45	0.48

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Hematocrit [L/L]	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	0.413 (0.028)	0.420 (0.040)	0.388 (0.040)	0.412 (0.021)	0.418 (0.030)	0.406 (0.047)	0.415 (0.031)	0.411 (0.035)
		Min	0.36	0.36	0.34	0.36	0.38	0.34	0.38	0.34
		Median	0.415	0.420	0.380	0.420	0.410	0.400	0.410	0.410
		Max	0.45	0.49	0.46	0.44	0.47	0.48	0.47	0.49
	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	0.397 (0.034)	0.420 (0.036)	0.399 (0.039)	0.411 (0.019)	0.415 (0.030)	0.409 (0.036)	0.423 (0.025)	0.411 (0.032)
		Min	0.35	0.35	0.36	0.38	0.35	0.34	0.39	0.34
		Median	0.400	0.425	0.380	0.410	0.420	0.405	0.425	0.410
		Max	0.47	0.47	0.47	0.45	0.47	0.47	0.47	0.47
Hemoglobin (Blood) [mmol/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	8.62 (0.90)	8.93 (0.98)	8.53 (0.56)	9.05 (0.45)	8.88 (0.49)	9.02 (0.81)	8.98 (0.65)	8.86 (0.72)
		Min	7.4	7.4	7.6	8.2	8.1	7.7	7.7	7.4
		Median	8.40	8.70	8.40	9.10	8.80	8.65	9.20	8.75
		Max	10.4	10.4	9.4	9.7	9.6	10.3	9.9	10.4

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Hemoglobin (Blood) [mmol/L]	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	8.51 (0.82)	8.66 (0.87)	8.05 (0.74)	8.97 (0.48)	8.78 (0.62)	8.93 (0.88)	8.59 (0.59)	8.64 (0.76)
		Min	7.1	7.2	7.2	8.1	7.7	7.4	7.8	7.1
		Median	8.35	8.60	7.85	8.90	8.75	8.85	8.60	8.65
		Max	10.2	9.9	9.3	9.7	9.7	10.4	9.7	10.4
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	8.31 (0.85)	8.51 (0.99)	7.94 (0.61)	8.72 (0.40)	8.69 (0.56)	8.48 (0.84)	8.30 (0.52)	8.42 (0.73)
		Min	7.3	6.7	7.2	8.1	7.7	7.2	7.3	6.7
		Median	8.25	8.60	7.85	8.75	8.90	8.25	8.45	8.50
		Max	10.2	9.7	8.9	9.2	9.3	9.9	8.9	10.2
	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	8.43 (0.92)	8.58 (0.95)	7.91 (0.80)	8.74 (0.50)	8.49 (0.62)	8.32 (0.80)	8.48 (0.63)	8.42 (0.77)
		Min	7.1	7.3	7.0	8.0	7.8	6.8	7.8	6.8
		Median	8.40	8.40	7.80	8.90	8.35	8.20	8.30	8.40
		Max	10.2	9.9	9.4	9.4	9.7	9.8	9.5	10.2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Hemoglobin (Blood) [mmol/L]	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	8.44 (0.74)	8.58 (1.05)	7.95 (0.79)	8.45 (0.39)	8.53 (0.53)	8.41 (0.99)	8.51 (0.62)	8.41 (0.76)
		Min	7.1	6.8	7.0	7.5	7.9	6.9	7.6	6.8
		Median	8.55	8.40	7.60	8.60	8.50	8.40	8.40	8.40
		Max	9.4	10.4	9.4	8.9	9.5	10.2	9.5	10.4
	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	8.10 (0.82)	8.51 (0.95)	8.11 (0.78)	8.55 (0.45)	8.51 (0.55)	8.43 (0.83)	8.63 (0.67)	8.41 (0.74)
		Min	6.9	6.9	7.1	7.7	7.5	6.8	7.8	6.8
		Median	8.10	8.40	7.70	8.60	8.55	8.35	8.50	8.40
		Max	9.9	9.8	9.5	9.4	9.4	9.8	10.0	10.0
Leukocytes (Blood) [10^9/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	5.83 (1.10)	6.49 (1.58)	6.91 (1.50)	6.10 (0.92)	6.37 (1.57)	6.02 (1.45)	5.67 (0.79)	6.20 (1.32)
		Min	3.8	3.9	4.5	4.8	4.9	3.8	4.0	3.8
		Median	5.50	6.60	6.60	6.00	5.45	5.95	5.65	6.00
		Max	8.3	9.4	9.6	7.6	9.0	9.4	7.3	9.6

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Leukocytes (Blood) [10^9/L]	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	5.39 (1.13)	5.78 (1.39)	6.18 (1.61)	5.82 (1.26)	5.73 (1.28)	6.28 (1.99)	5.66 (1.33)	5.83 (1.42)
		Min	3.3	3.6	3.8	4.1	4.3	3.4	3.9	3.3
		Median	5.65	5.75	6.10	5.70	5.40	5.55	5.20	5.70
		Max	6.6	8.1	9.1	7.9	8.0	10.4	8.2	10.4
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	5.28 (0.93)	6.23 (1.74)	5.87 (1.76)	6.18 (0.95)	5.22 (1.21)	6.06 (1.48)	5.86 (1.35)	5.81 (1.38)
		Min	4.0	3.3	2.7	4.9	3.6	4.1	3.8	2.7
		Median	5.05	6.70	5.65	6.25	5.00	5.85	6.05	5.65
		Max	6.8	8.7	8.9	7.5	7.5	9.5	7.4	9.5
	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	5.07 (1.03)	5.67 (1.65)	5.71 (1.48)	5.55 (1.16)	5.10 (1.11)	5.47 (1.47)	5.01 (1.27)	5.37 (1.31)
		Min	3.5	3.7	3.1	4.0	3.8	3.3	3.2	3.1
		Median	4.95	5.20	5.20	5.55	4.90	5.25	4.65	5.15
		Max	6.8	8.9	8.4	7.6	7.8	8.7	7.5	8.9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Leukocytes (Blood) [10^9/L]	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	5.51 (1.64)	6.08 (1.28)	6.75 (2.47)	5.41 (1.26)	5.68 (1.93)	5.75 (1.76)	5.33 (1.23)	5.78 (1.69)
		Min	3.8	3.7	4.9	3.9	3.2	2.9	3.8	2.9
		Median	5.10	6.45	5.90	4.90	5.40	5.70	5.40	5.60
		Max	9.9	7.6	13.4	7.4	11.0	8.9	7.9	13.4
	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	5.11 (0.76)	6.00 (1.56)	6.35 (1.35)	5.35 (1.09)	5.68 (2.10)	5.82 (1.29)	5.34 (1.20)	5.66 (1.40)
		Min	3.8	3.8	4.7	3.8	3.4	4.1	3.9	3.4
		Median	5.00	6.05	6.00	5.00	5.30	5.35	5.60	5.40
		Max	6.6	8.1	8.7	7.4	11.9	8.0	7.0	11.9
Lymphocytes (Blood) [10^9/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	1.874 (0.559)	1.847 (0.540)	2.027 (0.558)	1.772 (0.488)	2.016 (0.477)	1.896 (0.444)	1.743 (0.389)	1.882 (0.490)
		Min	1.10	0.98	0.83	1.01	0.98	1.11	1.10	0.83
		Median	1.775	1.790	2.030	1.710	2.060	1.880	1.700	1.880
		Max	3.08	3.22	3.10	2.87	2.81	2.55	2.56	3.22

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Lymphocytes (Blood) [10^9/L]	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	1.838 (0.534)	1.608 (0.508)	1.942 (0.535)	1.703 (0.518)	1.908 (0.248)	1.784 (0.414)	1.704 (0.337)	1.784 (0.452)
		Min	1.13	0.98	0.78	1.11	1.53	1.10	1.19	0.78
		Median	1.745	1.435	2.015	1.565	1.900	1.660	1.645	1.710
		Max	2.80	2.86	2.86	2.71	2.24	2.69	2.48	2.86
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	1.570 (0.315)	1.376 (0.399)	1.155 (0.491)	0.913 (0.256)	0.922 (0.254)	0.684 (0.205)	0.748 (0.269)	1.053 (0.438)
		Min	1.17	0.74	0.40	0.65	0.50	0.40	0.43	0.40
		Median	1.485	1.345	1.135	0.850	0.905	0.655	0.665	0.950
		Max	2.05	2.26	2.12	1.53	1.35	1.10	1.29	2.26
	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	1.707 (0.477)	1.838 (0.597)	1.938 (0.507)	1.834 (0.711)	1.925 (0.485)	1.813 (0.236)	1.772 (0.517)	1.832 (0.508)
		Min	1.08	1.33	0.88	1.26	1.24	1.39	0.97	0.88
		Median	1.645	1.705	1.895	1.625	1.920	1.770	1.655	1.760
		Max	2.85	3.38	2.98	3.71	2.97	2.16	2.84	3.71

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Lymphocytes (Blood) [10^9/L]	Day 29	n	12	12	11	11	12	9	12	79
		Mean (SD)	2.093 (0.788)	1.827 (0.449)	2.266 (0.594)	1.854 (0.532)	2.205 (0.618)	2.011 (0.423)	1.683 (0.420)	1.989 (0.579)
		Min	1.44	1.02	0.77	1.33	1.34	1.11	1.01	0.77
		Median	1.895	1.770	2.380	1.790	2.100	2.000	1.585	1.980
		Max	4.33	2.76	3.24	2.85	3.31	2.67	2.55	4.33
	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	1.871 (0.391)	1.825 (0.564)	1.975 (0.457)	1.652 (0.518)	1.910 (0.483)	1.991 (0.422)	1.718 (0.526)	1.847 (0.482)
		Min	1.22	1.07	0.87	1.19	1.39	1.36	1.06	0.87
		Median	1.800	1.640	1.970	1.530	1.740	1.910	1.565	1.800
		Max	2.71	3.29	2.66	2.95	2.93	3.05	2.75	3.29
Lymphocytes (Blood Smear) [10^9/L]	Day 1	n	0	0	0	0	0	0	0	0
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
		Min	-	-	-	-	-	-	-	-
		Median	-	-	-	-	-	-	-	-
		Max	-	-	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Lymphocytes (Blood Smear) [10^9/L]	Day 29	n	0	0	0	0	0	2	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	2.05 (-)	- (-)	2.05 (-)
		Min	-	-	-	-	-	2.0	-	2.0
		Median	-	-	-	-	-	2.05	-	2.05
		Max	-	-	-	-	-	2.1	-	2.1
Lymphocytes/Leukocytes (Blood) [%]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	32.62 (8.13)	29.28 (8.35)	29.88 (7.85)	29.13 (6.87)	32.57 (8.15)	31.95 (5.60)	30.91 (6.38)	30.90 (7.26)
		Min	13.3	14.8	12.7	18.1	19.0	20.9	24.1	12.7
		Median	32.25	27.55	29.90	28.95	33.70	31.90	29.50	30.15
		Max	45.3	45.1	40.7	41.5	43.0	40.5	45.7	45.7
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	33.96 (5.50)	28.04 (5.96)	32.23 (8.20)	29.57 (6.99)	34.68 (8.26)	29.62 (5.64)	30.87 (6.00)	31.28 (6.88)
		Min	26.7	18.6	12.5	18.4	22.8	17.5	20.8	12.5
		Median	33.10	28.70	33.25	27.40	34.60	30.35	31.20	30.60
		Max	43.4	38.2	45.4	40.5	49.9	39.4	42.0	49.9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Lymphocytes/Leukocytes (Blood) [%]	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	29.98 (5.31)	22.62 (4.77)	19.31 (4.44)	14.83 (3.52)	18.48 (7.13)	11.47 (2.86)	12.93 (3.91)	18.52 (7.49)
		Min	24.1	14.0	11.3	10.3	11.1	7.5	7.7	7.5
		Median	28.15	22.40	21.35	13.60	17.50	11.70	12.95	17.80
		Max	40.3	32.7	24.5	20.4	37.4	16.3	19.6	40.3
	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	33.64 (5.84)	32.90 (6.16)	35.00 (9.30)	32.97 (9.18)	38.13 (7.63)	34.91 (8.16)	35.73 (7.00)	34.75 (7.62)
		Min	27.9	21.1	18.3	22.6	27.5	20.4	21.5	18.3
		Median	31.40	33.45	34.45	30.10	37.65	33.45	37.75	33.55
		Max	45.3	41.5	52.9	48.8	49.1	49.1	48.1	52.9
	Day 29	n	12	12	11	11	12	9	12	79
		Mean (SD)	37.68 (4.45)	30.47 (6.17)	35.22 (10.31)	34.32 (5.81)	39.99 (8.66)	34.46 (7.06)	32.43 (8.02)	34.96 (7.75)
		Min	31.7	21.2	13.7	27.0	25.8	22.2	16.8	13.7
		Median	36.30	27.95	38.10	34.00	40.60	35.80	34.45	34.60
		Max	45.5	41.6	49.6	46.0	52.7	41.7	44.4	52.7

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Lymphocytes/Leukocytes (Blood) [%]	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	36.53 (4.55)	31.28 (8.45)	31.98 (8.56)	31.05 (7.22)	34.91 (7.18)	35.04 (7.16)	32.46 (7.43)	33.30 (7.33)
		Min	28.8	20.8	15.2	20.1	24.6	22.8	22.2	15.2
		Median	36.00	28.40	34.50	29.55	34.80	36.70	31.90	34.75
		Max	44.6	45.7	42.9	41.9	46.8	45.4	43.1	46.8
Lymphocytes/Leukocytes (Blood Smear) [%]	Day 1	n	0	0	0	0	0	0	0	0
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
		Min	-	-	-	-	-	-	-	-
		Median	-	-	-	-	-	-	-	-
		Max	-	-	-	-	-	-	-	-
	Day 29	n	0	0	0	0	0	2	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	48.0 (-)	- (-)	48.0 (-)
		Min	-	-	-	-	-	45	-	45
		Median	-	-	-	-	-	48.0	-	48.0
		Max	-	-	-	-	-	51	-	51

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

Program: Tfsaf_LB_2_1.sas (Page 24 of 74)

Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Monocytes (Blood) [10^9/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.463 (0.143)	0.538 (0.142)	0.537 (0.118)	0.539 (0.111)	0.506 (0.162)	0.518 (0.157)	0.478 (0.124)	0.511 (0.136)
		Min	0.24	0.36	0.35	0.29	0.31	0.33	0.32	0.24
		Median	0.445	0.520	0.525	0.525	0.475	0.470	0.455	0.490
		Max	0.67	0.81	0.76	0.73	0.86	0.86	0.81	0.86
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.482 (0.191)	0.499 (0.127)	0.504 (0.095)	0.497 (0.103)	0.489 (0.128)	0.513 (0.110)	0.480 (0.100)	0.495 (0.122)
		Min	0.27	0.32	0.35	0.32	0.32	0.33	0.31	0.27
		Median	0.390	0.480	0.505	0.505	0.485	0.505	0.490	0.495
		Max	0.80	0.71	0.65	0.66	0.72	0.66	0.68	0.80
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.546 (0.185)	0.593 (0.138)	0.601 (0.148)	0.766 (0.217)	0.635 (0.196)	0.679 (0.172)	0.708 (0.172)	0.647 (0.185)
		Min	0.36	0.41	0.34	0.45	0.37	0.42	0.41	0.34
		Median	0.475	0.570	0.630	0.725	0.620	0.690	0.695	0.655
		Max	0.86	0.86	0.81	1.12	0.95	0.98	1.06	1.12

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

Program: Tfsaf_LB_2_1.sas (Page 25 of 74)

Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Monocytes (Blood) [10^9/L]	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.458 (0.149)	0.498 (0.161)	0.428 (0.089)	0.456 (0.102)	0.384 (0.074)	0.418 (0.116)	0.378 (0.106)	0.431 (0.120)
		Min	0.30	0.20	0.29	0.28	0.28	0.20	0.19	0.19
		Median	0.400	0.480	0.405	0.450	0.360	0.410	0.385	0.410
		Max	0.74	0.82	0.53	0.63	0.53	0.65	0.52	0.82
	Day 29	n	12	12	11	11	12	9	12	79
		Mean (SD)	0.478 (0.133)	0.521 (0.105)	0.515 (0.110)	0.479 (0.136)	0.446 (0.138)	0.526 (0.158)	0.492 (0.113)	0.492 (0.125)
		Min	0.33	0.36	0.36	0.28	0.26	0.27	0.32	0.26
		Median	0.470	0.550	0.500	0.480	0.440	0.520	0.495	0.490
		Max	0.71	0.65	0.75	0.78	0.63	0.76	0.62	0.78
	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	0.465 (0.117)	0.491 (0.125)	0.553 (0.096)	0.477 (0.120)	0.474 (0.146)	0.510 (0.126)	0.437 (0.121)	0.486 (0.123)
		Min	0.36	0.29	0.42	0.31	0.28	0.38	0.30	0.28
		Median	0.460	0.475	0.550	0.465	0.435	0.460	0.405	0.465
		Max	0.75	0.70	0.73	0.76	0.69	0.78	0.69	0.78

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Monocytes (Blood Smear) [10^9/L]	Day 1	n	0	0	0	0	0	0	0	0
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
		Min	-	-	-	-	-	-	-	-
		Median	-	-	-	-	-	-	-	-
		Max	-	-	-	-	-	-	-	-
	Day 29	n	0	0	0	0	0	2	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	0.195 (-)	- (-)	0.195 (-)
		Min	-	-	-	-	-	0.18	-	0.18
		Median	-	-	-	-	-	0.195	-	0.195
		Max	-	-	-	-	-	0.21	-	0.21
Monocytes/Leukocytes (Blood) [%]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	8.15 (2.64)	8.37 (1.23)	7.85 (1.25)	8.90 (1.62)	7.93 (1.49)	8.68 (1.86)	8.51 (2.22)	8.34 (1.79)
		Min	4.2	5.9	5.2	5.2	5.3	5.6	6.1	4.2
		Median	9.00	8.15	7.90	9.40	8.50	9.15	8.00	8.60
		Max	11.9	10.5	9.4	11.1	9.7	12.5	14.2	14.2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Monocytes/Leukocytes (Blood) [%]	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	8.85 (2.51)	8.76 (1.62)	8.45 (1.92)	8.75 (1.91)	8.53 (1.16)	8.47 (1.66)	8.78 (2.49)	8.66 (1.88)
		Min	5.3	6.5	5.9	4.9	6.6	5.8	6.1	4.9
		Median	8.70	9.05	8.50	9.25	8.25	8.45	8.20	8.60
		Max	12.5	11.1	11.7	11.0	10.8	11.8	14.7	14.7
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	10.25 (2.56)	9.91 (2.35)	10.76 (3.01)	12.53 (3.49)	12.47 (3.83)	11.40 (2.54)	12.64 (4.25)	11.42 (3.28)
		Min	6.9	7.6	7.4	7.9	7.6	7.6	8.4	6.9
		Median	10.35	9.20	9.65	12.95	11.65	11.55	11.00	10.80
		Max	14.5	15.4	15.9	18.1	19.9	15.0	20.7	20.7
	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	9.07 (2.19)	8.77 (1.60)	7.67 (1.26)	8.33 (1.54)	7.69 (1.44)	7.70 (1.21)	7.78 (2.45)	8.14 (1.75)
		Min	5.6	5.4	5.6	5.8	5.0	5.7	5.0	5.0
		Median	8.75	8.95	7.65	8.85	7.90	7.50	7.30	8.05
		Max	12.1	11.2	10.0	9.9	10.1	10.1	13.8	13.8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Monocytes/Leukocytes (Blood) [%]	Day 29	n	12	12	11	11	12	9	12	79
		Mean (SD)	9.01 (2.33)	8.68 (1.13)	7.96 (1.48)	8.92 (1.67)	8.08 (2.05)	8.71 (1.32)	9.40 (2.20)	8.68 (1.81)
		Min	4.6	6.7	5.6	5.7	5.6	5.9	7.5	4.6
		Median	9.45	8.85	7.70	9.30	8.10	9.00	8.70	8.60
		Max	12.0	10.2	10.2	10.7	11.3	10.3	15.2	15.2
	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	9.25 (2.52)	8.29 (1.27)	8.88 (1.43)	8.98 (1.72)	8.63 (2.25)	8.92 (1.83)	8.54 (2.92)	8.78 (2.01)
		Min	5.4	6.7	6.3	6.0	5.8	5.7	4.6	4.6
		Median	9.00	8.00	9.50	9.30	8.40	8.50	8.20	8.50
		Max	13.0	10.6	10.4	11.9	12.2	12.4	13.8	13.8
Monocytes/Leukocytes (Blood Smear) [%]	Day 1	n	0	0	0	0	0	0	0	0
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
		Min	-	-	-	-	-	-	-	-
		Median	-	-	-	-	-	-	-	-
		Max	-	-	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Monocytes/Leukocytes (Blood Smear) [%]	Day 29	n	0	0	0	0	0	2	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	4.5 (-)	- (-)	4.5 (-)
		Min	-	-	-	-	-	4	-	4
		Median	-	-	-	-	-	4.5	-	4.5
		Max	-	-	-	-	-	5	-	5
Neutrophils (Blood) [10^9/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	3.292 (1.187)	3.886 (1.399)	4.064 (1.213)	3.518 (0.667)	3.645 (1.326)	3.364 (1.053)	3.280 (0.730)	3.578 (1.110)
		Min	1.97	2.05	2.24	2.15	2.32	2.14	2.44	1.97
		Median	3.145	3.925	4.160	3.705	3.200	3.335	3.165	3.345
		Max	6.79	7.22	5.92	4.32	6.28	5.65	5.00	7.22
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	2.862 (0.613)	3.489 (0.974)	3.478 (1.279)	3.376 (0.986)	3.138 (1.211)	3.747 (1.615)	3.307 (1.209)	3.342 (1.151)
		Min	1.76	1.80	1.64	1.90	1.69	1.85	2.30	1.64
		Median	2.930	3.425	3.375	3.140	2.645	3.225	2.670	3.145
		Max	3.71	5.38	5.76	5.55	5.26	7.63	5.85	7.63

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Neutrophils (Blood) [10^9/L]	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	2.966 (0.640)	4.063 (1.298)	3.876 (1.211)	4.319 (0.833)	3.553 (1.136)	4.568 (1.163)	4.317 (1.207)	3.952 (1.169)
		Min	2.19	1.98	1.66	3.20	1.49	2.92	2.39	1.49
		Median	2.855	4.305	3.790	4.385	3.535	4.485	4.270	3.700
		Max	4.28	5.56	5.95	5.77	5.91	6.96	5.68	6.96
	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	2.703 (0.585)	3.108 (1.045)	3.119 (1.184)	3.029 (0.770)	2.605 (0.804)	3.011 (1.309)	2.709 (0.951)	2.898 (0.963)
		Min	1.97	1.92	1.11	1.68	1.45	1.42	1.69	1.11
		Median	2.645	2.745	2.910	3.095	2.555	2.635	2.425	2.695
		Max	3.44	5.03	5.01	3.93	4.24	6.15	5.19	6.15
	Day 29	n	12	12	11	11	12	9	12	79
		Mean (SD)	2.692 (0.790)	3.506 (0.936)	3.687 (2.119)	2.870 (0.718)	2.743 (1.383)	3.267 (1.475)	3.008 (1.115)	3.100 (1.286)
		Min	1.71	2.05	1.88	1.54	1.13	1.39	1.91	1.13
		Median	2.520	3.715	3.000	2.960	2.435	3.000	2.815	2.820
		Max	4.54	4.90	9.18	3.78	6.52	6.08	5.82	9.18

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Neutrophils (Blood) [10^9/L]	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	2.534 (0.488)	3.485 (1.207)	3.527 (1.248)	2.942 (0.705)	2.974 (1.485)	3.075 (1.057)	3.003 (0.963)	3.078 (1.078)
		Min	1.69	1.75	2.13	1.92	1.33	1.64	1.92	1.33
		Median	2.300	3.365	3.240	2.990	2.725	2.740	2.855	2.845
		Max	3.28	5.18	6.06	3.97	7.26	4.88	4.85	7.26
Neutrophils (Blood Smear) [10^9/L]	Day 1	n	0	0	0	0	0	0	0	0
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
		Min	-	-	-	-	-	-	-	-
		Median	-	-	-	-	-	-	-	-
		Max	-	-	-	-	-	-	-	-
	Day 29	n	0	0	0	0	0	2	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	1.25 (-)	- (-)	1.25 (-)
		Min	-	-	-	-	-	1.2	-	1.2
		Median	-	-	-	-	-	1.25	-	1.25
		Max	-	-	-	-	-	1.3	-	1.3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Neutrophils/Leukocytes (Blood) [%]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	55.65 (9.79)	59.03 (9.58)	58.17 (9.21)	57.66 (7.77)	56.15 (8.40)	55.34 (6.40)	57.63 (6.73)	57.09 (8.16)
		Min	45.9	38.6	45.0	44.7	46.4	43.7	43.8	38.6
		Median	51.80	60.60	58.30	58.20	55.60	54.50	58.45	57.75
		Max	81.8	76.8	76.7	74.5	70.6	67.8	68.5	81.8
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	53.16 (4.16)	60.03 (7.10)	55.09 (9.44)	57.50 (7.36)	53.20 (9.17)	58.18 (6.67)	57.22 (7.74)	56.34 (7.67)
		Min	48.2	50.1	41.3	46.3	39.3	50.0	47.4	39.3
		Median	52.55	59.10	52.55	58.65	50.55	57.55	54.20	55.80
		Max	60.9	72.7	77.0	70.2	69.5	73.4	71.3	77.0
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	55.98 (4.61)	64.38 (5.31)	66.05 (5.30)	69.71 (5.46)	66.98 (9.38)	75.23 (4.08)	73.00 (5.93)	67.33 (8.21)
		Min	50.0	52.6	59.7	63.5	41.3	69.7	62.6	41.3
		Median	56.20	63.55	65.65	68.60	69.20	75.80	73.55	67.40
		Max	63.0	73.2	75.2	78.5	78.8	82.1	81.5	82.1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Neutrophils/Leukocytes (Blood) [%]	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	53.33 (4.28)	54.48 (6.93)	53.33 (10.48)	54.52 (9.15)	50.48 (8.43)	53.23 (8.81)	53.62 (7.71)	53.28 (7.98)
		Min	44.8	45.9	35.9	39.9	38.2	43.0	42.8	35.9
		Median	54.00	51.80	53.70	55.10	51.55	51.45	51.20	53.15
		Max	60.8	69.5	70.8	65.6	65.4	70.7	69.2	70.8
	Day 29	n	12	12	11	11	12	9	12	79
		Mean (SD)	48.95 (4.28)	57.32 (6.82)	52.17 (12.31)	53.02 (6.56)	46.88 (9.70)	52.08 (8.37)	55.34 (8.59)	52.25 (8.75)
		Min	43.1	44.6	35.5	39.6	35.4	44.7	46.0	35.4
		Median	49.00	58.35	49.60	54.10	45.15	48.10	52.95	51.40
		Max	57.7	68.0	74.4	64.2	67.2	68.3	73.7	74.4
	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	49.41 (4.28)	57.23 (8.76)	54.47 (10.01)	55.07 (8.30)	50.96 (8.48)	51.81 (8.30)	55.69 (8.32)	53.56 (8.36)
		Min	44.6	41.2	40.7	40.9	39.2	40.0	45.6	39.2
		Median	48.80	60.00	52.50	56.25	48.60	50.10	53.60	52.15
		Max	57.6	70.1	72.3	67.3	65.7	67.7	70.5	72.3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Neutrophils/Leukocytes (Blood Smear) [%]	Day 1	n	0	0	0	0	0	0	0	0
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
		Min	-	-	-	-	-	-	-	-
		Median	-	-	-	-	-	-	-	-
		Max	-	-	-	-	-	-	-	-
	Day 29	n	0	0	0	0	0	2	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	29.0 (-)	- (-)	29.0 (-)
		Min	-	-	-	-	-	29	-	29
		Median	-	-	-	-	-	29.0	-	29.0
		Max	-	-	-	-	-	29	-	29
Platelets [10^9/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	252.8 (39.1)	250.3 (50.5)	270.2 (31.2)	249.8 (41.1)	236.3 (28.2)	257.6 (40.3)	245.6 (59.6)	251.8 (42.2)
		Min	211	173	211	179	181	193	155	155
		Median	242.5	255.5	265.5	246.0	236.5	264.5	242.0	253.0
		Max	355	331	336	328	290	318	368	368

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Platelets [10^9/L]	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	244.2 (41.5)	237.8 (44.5)	252.5 (33.0)	240.3 (43.1)	225.8 (35.6)	249.4 (40.2)	233.8 (62.2)	240.5 (43.0)
		Min	167	171	194	175	178	195	160	160
		Median	248.5	226.0	257.0	241.5	214.0	242.5	222.0	243.0
		Max	324	327	307	314	284	321	345	345
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	230.7 (35.6)	234.9 (42.7)	234.3 (37.5)	228.3 (40.4)	203.7 (34.0)	218.4 (33.8)	207.2 (56.3)	222.5 (41.0)
		Min	192	170	173	168	162	172	147	147
		Median	220.5	230.0	236.5	224.5	202.5	215.0	199.0	223.0
		Max	298	311	303	305	264	281	306	311
	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	257.1 (54.5)	248.5 (40.2)	242.2 (39.7)	257.6 (52.3)	238.6 (34.5)	236.8 (38.0)	239.4 (52.0)	245.7 (44.2)
		Min	202	184	159	186	208	183	162	159
		Median	240.0	234.5	252.5	273.0	224.0	232.0	235.5	237.5
		Max	390	307	295	340	314	288	316	390

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Platelets [10^9/L]	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	256.8 (60.5)	237.8 (63.7)	264.4 (44.2)	237.5 (42.6)	227.3 (27.2)	221.9 (44.3)	225.0 (56.9)	238.6 (50.5)
		Min	196	103	182	176	180	161	150	103
		Median	245.5	237.0	262.0	245.0	222.0	223.0	224.0	237.0
		Max	428	330	338	321	279	295	341	428
	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	248.7 (48.3)	255.4 (44.0)	248.9 (37.9)	230.7 (40.5)	227.1 (30.3)	245.8 (39.1)	234.3 (58.4)	241.4 (43.0)
		Min	184	174	189	174	175	182	168	168
		Median	230.0	258.0	247.0	237.0	226.0	245.0	219.5	237.0
		Max	326	317	337	301	278	303	351	351

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Basophils (Blood) [10^9/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	0.048 (0.011)	0.051 (0.015)	0.040 (0.022)	0.046 (0.017)	0.046 (0.022)
		Min	0.03	0.03	0.02	0.02	0.01
		Median	0.050	0.055	0.035	0.045	0.040
		Max	0.07	0.08	0.10	0.10	0.13
	Day 1	n	11	10	12	33	117
		Mean (SD)	0.050 (0.015)	0.057 (0.019)	0.045 (0.018)	0.050 (0.018)	0.046 (0.021)
		Min	0.03	0.04	0.01	0.01	0.01
		Median	0.050	0.050	0.045	0.050	0.040
		Max	0.07	0.10	0.07	0.10	0.13
	Day 2	n	12	12	12	36	120
		Mean (SD)	0.038 (0.011)	0.041 (0.018)	0.035 (0.012)	0.038 (0.014)	0.036 (0.018)
		Min	0.02	0.01	0.02	0.01	0.01
		Median	0.035	0.040	0.035	0.040	0.030
		Max	0.06	0.07	0.05	0.07	0.09

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Basophils (Blood) [10^9/L]	Day 8	n	12	12	12	36	120
		Mean (SD)	0.041 (0.009)	0.034 (0.014)	0.034 (0.018)	0.036 (0.014)	0.035 (0.017)
		Min	0.03	0.01	0.01	0.01	0.01
		Median	0.040	0.035	0.030	0.040	0.030
		Max	0.06	0.06	0.07	0.07	0.09
	Day 29	n	12	11	12	35	114
		Mean (SD)	0.046 (0.014)	0.043 (0.013)	0.033 (0.017)	0.041 (0.016)	0.040 (0.017)
		Min	0.02	0.03	0.01	0.01	0.01
		Median	0.050	0.040	0.030	0.040	0.040
		Max	0.07	0.08	0.07	0.08	0.11
	Day 50	n	12	0	0	12	94
		Mean (SD)	0.048 (0.015)	- (-)	- (-)	0.048 (0.015)	0.046 (0.021)
		Min	0.02	-	-	0.02	0.01
		Median	0.040	-	-	0.040	0.040
		Max	0.08	-	-	0.08	0.11

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Basophils (Blood Smear) [10^9/L]	Day 1	n	0	2	0	2	2
		Mean (SD)	- (-)	0.000 (-)	- (-)	0.000 (-)	0.000 (-)
		Min	-	0.00	-	0.00	0.00
		Median	-	0.000	-	0.000	0.000
		Max	-	0.00	-	0.00	0.00
	Day 29	n	0	1	0	1	3
		Mean (SD)	- (-)	0.000 (-)	- (-)	0.000 (-)	0.030 (0.052)
		Min	-	0.00	-	0.00	0.00
		Median	-	0.000	-	0.000	0.000
		Max	-	0.00	-	0.00	0.09
Basophils/Leukocytes (Blood) [%]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	0.76 (0.21)	0.97 (0.28)	0.70 (0.49)	0.81 (0.35)	0.77 (0.36)
		Min	0.5	0.5	0.2	0.2	0.1
		Median	0.75	1.05	0.55	0.70	0.70
		Max	1.3	1.4	2.0	2.0	2.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Basophils/Leukocytes (Blood) [%]	Day 1	n	11	10	12	33	117
		Mean (SD)	0.86 (0.28)	1.11 (0.36)	0.79 (0.36)	0.91 (0.35)	0.81 (0.36)
		Min	0.4	0.7	0.2	0.2	0.2
		Median	0.90	0.95	0.75	0.90	0.80
		Max	1.3	1.8	1.6	1.8	1.8
	Day 2	n	12	12	12	36	120
		Mean (SD)	0.73 (0.25)	0.78 (0.31)	0.63 (0.25)	0.71 (0.27)	0.64 (0.29)
		Min	0.4	0.2	0.3	0.2	0.1
		Median	0.70	0.80	0.60	0.70	0.60
		Max	1.1	1.3	1.2	1.3	1.7
	Day 8	n	12	12	12	36	120
		Mean (SD)	0.77 (0.18)	0.73 (0.30)	0.61 (0.38)	0.70 (0.30)	0.68 (0.30)
		Min	0.5	0.2	0.2	0.2	0.2
		Median	0.70	0.75	0.50	0.70	0.70
		Max	1.2	1.3	1.4	1.4	1.5

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Basophils/Leukocytes (Blood) [%]	Day 29	n	12	11	12	35	114
		Mean (SD)	0.84 (0.30)	0.96 (0.26)	0.63 (0.36)	0.81 (0.33)	0.73 (0.31)
		Min	0.3	0.7	0.3	0.3	0.3
		Median	0.80	0.90	0.60	0.80	0.70
		Max	1.4	1.4	1.6	1.6	1.7
	Day 50	n	12	0	0	12	94
		Mean (SD)	0.90 (0.26)	- (-)	- (-)	0.90 (0.26)	0.81 (0.32)
		Min	0.4	-	-	0.4	0.2
		Median	0.80	-	-	0.80	0.80
		Max	1.3	-	-	1.3	1.6
Basophils/Leukocytes (Blood Smear) [%]	Day 1	n	0	2	0	2	2
		Mean (SD)	- (-)	0.0 (-)	- (-)	0.0 (-)	0.0 (-)
		Min	-	0	-	0	0
		Median	-	0.0	-	0.0	0.0
		Max	-	0	-	0	0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Basophils/Leukocytes (Blood Smear) [%]	Day 29	n	0	1	0	1	3
		Mean (SD)	- (-)	0.0 (-)	- (-)	0.0 (-)	0.7 (1.2)
		Min	-	0	-	0	0
		Median	-	0.0	-	0.0	0.0
		Max	-	0	-	0	2
Eosinophils (Blood) [10^9/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	0.156 (0.078)	0.178 (0.098)	0.148 (0.101)	0.161 (0.091)	0.174 (0.112)
		Min	0.05	0.07	0.04	0.04	0.03
		Median	0.150	0.155	0.110	0.145	0.140
		Max	0.27	0.36	0.37	0.37	0.58
	Day 1	n	11	10	12	33	117
		Mean (SD)	0.171 (0.085)	0.179 (0.101)	0.182 (0.131)	0.177 (0.105)	0.171 (0.108)
		Min	0.05	0.06	0.06	0.05	0.02
		Median	0.160	0.170	0.130	0.160	0.140
		Max	0.30	0.41	0.49	0.49	0.51

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Eosinophils (Blood) [10^9/L]	Day 2	n	12	12	12	36	120
		Mean (SD)	0.145 (0.073)	0.136 (0.080)	0.131 (0.119)	0.137 (0.090)	0.130 (0.098)
		Min	0.03	0.05	0.04	0.03	0.01
		Median	0.135	0.125	0.095	0.120	0.110
		Max	0.24	0.32	0.47	0.47	0.57
	Day 8	n	12	12	12	36	120
		Mean (SD)	0.175 (0.078)	0.172 (0.113)	0.216 (0.187)	0.188 (0.132)	0.174 (0.115)
		Min	0.07	0.04	0.04	0.04	0.03
		Median	0.165	0.150	0.150	0.155	0.150
		Max	0.30	0.43	0.72	0.72	0.72
	Day 29	n	12	11	12	35	114
		Mean (SD)	0.218 (0.132)	0.214 (0.165)	0.208 (0.151)	0.213 (0.145)	0.202 (0.129)
		Min	0.09	0.07	0.04	0.04	0.03
		Median	0.190	0.150	0.165	0.180	0.180
		Max	0.54	0.55	0.57	0.57	0.57

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Eosinophils (Blood) [10^9/L]	Day 50	n	12	0	0	12	94
		Mean (SD)	0.173 (0.077)	- (-)	- (-)	0.173 (0.077)	0.202 (0.157)
		Min	0.07	-	-	0.07	0.02
		Median	0.160	-	-	0.160	0.170
		Max	0.34	-	-	0.34	0.95
Eosinophils (Blood Smear) [10^9/L]	Day 1	n	0	2	0	2	2
		Mean (SD)	- (-)	0.080 (-)	- (-)	0.080 (-)	0.080 (-)
		Min	-	0.00	-	0.00	0.00
		Median	-	0.080	-	0.080	0.080
		Max	-	0.16	-	0.16	0.16
	Day 29	n	0	1	0	1	3
		Mean (SD)	- (-)	0.040 (-)	- (-)	0.040 (-)	0.097 (0.049)
		Min	-	0.04	-	0.04	0.04
		Median	-	0.040	-	0.040	0.120
		Max	-	0.04	-	0.04	0.13

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Eosinophils/Leukocytes (Blood) [%]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	2.39 (1.16)	3.32 (1.52)	2.43 (1.79)	2.71 (1.53)	2.85 (1.76)
		Min	1.0	1.0	0.7	0.7	0.4
		Median	2.25	3.50	1.70	2.35	2.35
		Max	4.2	5.8	5.7	5.8	8.0
	Day 1	n	11	10	12	33	117
		Mean (SD)	2.95 (1.51)	3.43 (1.70)	3.15 (2.30)	3.17 (1.84)	3.02 (1.85)
		Min	1.0	1.0	1.0	1.0	0.3
		Median	2.50	3.25	2.20	2.70	2.60
		Max	5.4	6.1	7.3	7.3	7.8
	Day 2	n	12	12	12	36	120
		Mean (SD)	2.69 (1.21)	2.64 (1.50)	2.18 (1.40)	2.50 (1.35)	2.24 (1.51)
		Min	0.7	0.9	0.6	0.6	0.1
		Median	2.85	2.40	1.75	2.40	2.00
		Max	4.5	6.0	5.8	6.0	8.2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Eosinophils/Leukocytes (Blood) [%]	Day 8	n	12	12	12	36	120
		Mean (SD)	3.33 (1.57)	3.59 (2.12)	3.80 (3.09)	3.58 (2.29)	3.28 (2.01)
		Min	1.1	0.6	1.0	0.6	0.6
		Median	3.65	3.25	2.20	3.20	2.60
		Max	5.5	7.5	11.2	11.2	11.2
	Day 29	n	12	11	12	35	114
		Mean (SD)	3.80 (1.90)	4.58 (2.71)	3.87 (2.51)	4.07 (2.34)	3.62 (2.08)
		Min	1.2	1.6	1.2	1.2	0.6
		Median	3.35	4.10	3.15	3.50	3.20
		Max	8.4	9.3	8.5	9.3	9.3
	Day 50	n	12	0	0	12	94
		Mean (SD)	3.18 (1.20)	- (-)	- (-)	3.18 (1.20)	3.51 (2.40)
		Min	1.7	-	-	1.7	0.5
		Median	2.80	-	-	2.80	2.80
		Max	5.1	-	-	5.1	15.3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Eosinophils/Leukocytes (Blood Smear) [%]	Day 1	n	0	2	0	2	2
		Mean (SD)	- (-)	1.5 (-)	- (-)	1.5 (-)	1.5 (-)
		Min	-	0	-	0	0
		Median	-	1.5	-	1.5	1.5
		Max	-	3	-	3	3
	Day 29	n	0	1	0	1	3
		Mean (SD)	- (-)	1.0 (-)	- (-)	1.0 (-)	2.3 (1.2)
		Min	-	1	-	1	1
		Median	-	1.0	-	1.0	3.0
		Max	-	1	-	1	3
Erythrocytes (Blood) [10^{12}/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	4.68 (0.39)	4.49 (0.38)	4.68 (0.49)	4.62 (0.42)	4.73 (0.43)
		Min	4.2	4.0	4.1	4.0	3.8
		Median	4.65	4.40	4.50	4.50	4.70
		Max	5.6	5.2	5.6	5.6	5.9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Erythrocytes (Blood) [10^{12}/L]	Day 1	n	11	12	12	35	119
		Mean (SD)	4.65 (0.45)	4.28 (0.31)	4.68 (0.50)	4.53 (0.45)	4.62 (0.44)
		Min	4.2	3.7	4.1	3.7	3.5
		Median	4.50	4.30	4.65	4.50	4.60
		Max	5.8	4.7	5.6	5.8	5.9
	Day 2	n	12	12	12	36	120
		Mean (SD)	4.52 (0.32)	4.27 (0.34)	4.49 (0.49)	4.43 (0.40)	4.51 (0.43)
		Min	4.0	3.6	3.9	3.6	3.6
		Median	4.60	4.20	4.40	4.40	4.50
		Max	5.1	4.9	5.5	5.5	5.5
	Day 8	n	12	12	12	36	120
		Mean (SD)	4.56 (0.36)	4.21 (0.32)	4.53 (0.47)	4.43 (0.41)	4.52 (0.45)
		Min	3.9	3.6	4.0	3.6	3.6
		Median	4.60	4.25	4.45	4.40	4.50
		Max	5.3	4.7	5.4	5.4	5.9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Erythrocytes (Blood) [10^{12}/L]	Day 29	n	12	12	12	36	117
		Mean (SD)	4.53 (0.43)	4.23 (0.29)	4.48 (0.42)	4.42 (0.40)	4.53 (0.44)
		Min	3.7	3.6	4.1	3.6	3.6
		Median	4.50	4.25	4.30	4.35	4.50
		Max	5.3	4.7	5.3	5.3	5.9
	Day 50	n	12	0	0	12	94
		Mean (SD)	4.52 (0.44)	- (-)	- (-)	4.52 (0.44)	4.56 (0.42)
		Min	3.8	-	-	3.8	3.6
		Median	4.40	-	-	4.40	4.60
		Max	5.5	-	-	5.5	5.6
Hematocrit [L/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	0.428 (0.037)	0.439 (0.037)	0.422 (0.039)	0.430 (0.037)	0.431 (0.033)
		Min	0.38	0.38	0.38	0.38	0.37
		Median	0.420	0.430	0.420	0.420	0.430
		Max	0.50	0.52	0.50	0.52	0.52

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Hematocrit [L/L]	Day 1	n	11	12	12	35	119
		Mean (SD)	0.420 (0.032)	0.406 (0.024)	0.426 (0.039)	0.417 (0.033)	0.423 (0.032)
		Min	0.38	0.36	0.37	0.36	0.36
		Median	0.410	0.400	0.420	0.410	0.420
		Max	0.50	0.44	0.50	0.50	0.50
	Day 2	n	12	12	12	36	120
		Mean (SD)	0.410 (0.027)	0.407 (0.028)	0.409 (0.038)	0.409 (0.031)	0.412 (0.033)
		Min	0.37	0.35	0.37	0.35	0.34
		Median	0.410	0.405	0.400	0.405	0.410
		Max	0.45	0.45	0.48	0.48	0.48
	Day 8	n	12	12	12	36	120
		Mean (SD)	0.411 (0.027)	0.407 (0.028)	0.412 (0.036)	0.410 (0.030)	0.410 (0.035)
		Min	0.36	0.35	0.37	0.35	0.33
		Median	0.415	0.400	0.405	0.405	0.410
		Max	0.46	0.46	0.48	0.48	0.48

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Hematocrit [L/L]	Day 29	n	12	12	12	36	117
		Mean (SD)	0.413 (0.041)	0.394 (0.022)	0.405 (0.034)	0.404 (0.033)	0.409 (0.034)
		Min	0.34	0.34	0.38	0.34	0.34
		Median	0.400	0.390	0.390	0.400	0.410
		Max	0.47	0.42	0.48	0.48	0.49
	Day 50	n	12	0	0	12	94
		Mean (SD)	0.408 (0.037)	- (-)	- (-)	0.408 (0.037)	0.411 (0.032)
		Min	0.34	-	-	0.34	0.34
		Median	0.400	-	-	0.400	0.410
		Max	0.47	-	-	0.47	0.47
Hemoglobin (Blood) [mmol/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	8.82 (0.76)	8.45 (0.54)	8.73 (0.86)	8.66 (0.73)	8.80 (0.72)
		Min	7.9	7.7	7.8	7.7	7.4
		Median	8.55	8.35	8.65	8.45	8.70
		Max	10.2	9.3	10.6	10.6	10.6

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Hemoglobin (Blood) [mmol/L]	Day 1	n	11	12	12	35	119
		Mean (SD)	8.63 (0.71)	8.04 (0.45)	8.70 (0.88)	8.45 (0.75)	8.58 (0.76)
		Min	7.9	7.2	7.6	7.2	7.1
		Median	8.40	8.05	8.65	8.30	8.50
		Max	10.4	8.9	10.5	10.5	10.5
	Day 2	n	12	12	12	36	120
		Mean (SD)	8.43 (0.60)	7.99 (0.53)	8.35 (0.92)	8.26 (0.71)	8.37 (0.72)
		Min	7.6	6.8	7.4	6.8	6.7
		Median	8.40	8.05	8.25	8.25	8.40
		Max	9.5	8.7	10.1	10.1	10.2
	Day 8	n	12	12	12	36	120
		Mean (SD)	8.56 (0.70)	7.88 (0.42)	8.44 (0.81)	8.29 (0.71)	8.38 (0.75)
		Min	7.4	6.9	7.5	6.9	6.8
		Median	8.55	7.90	8.30	8.20	8.30
		Max	9.9	8.5	9.9	9.9	10.2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Hemoglobin (Blood) [mmol/L]	Day 29	n	12	12	12	36	117
		Mean (SD)	8.38 (0.80)	7.89 (0.45)	8.33 (0.78)	8.20 (0.71)	8.35 (0.75)
		Min	7.1	6.9	7.6	6.9	6.8
		Median	8.20	7.90	8.05	8.10	8.30
		Max	9.7	8.5	10.0	10.0	10.4
	Day 50	n	12	0	0	12	94
		Mean (SD)	8.41 (0.74)	- (-)	- (-)	8.41 (0.74)	8.41 (0.73)
		Min	7.2	-	-	7.2	6.8
		Median	8.20	-	-	8.20	8.40
		Max	9.7	-	-	9.7	10.0
Leukocytes (Blood) [10^9/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	6.55 (1.21)	5.53 (1.30)	6.30 (1.13)	6.13 (1.26)	6.18 (1.30)
		Min	4.6	3.6	4.2	3.6	3.6
		Median	6.50	5.70	6.40	6.30	6.10
		Max	9.1	7.6	8.1	9.1	9.6

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Leukocytes (Blood) [10^9/L]	Day 1	n	11	12	12	35	119
		Mean (SD)	5.94 (1.19)	5.27 (0.93)	5.95 (1.03)	5.71 (1.07)	5.80 (1.33)
		Min	4.1	3.3	4.4	3.3	3.3
		Median	6.20	5.35	5.95	5.90	5.70
		Max	8.2	6.7	7.9	8.2	10.4
	Day 2	n	12	12	12	36	120
		Mean (SD)	5.36 (1.18)	5.30 (0.95)	5.68 (1.49)	5.44 (1.20)	5.70 (1.34)
		Min	4.0	3.8	3.1	3.1	2.7
		Median	5.20	5.35	5.60	5.35	5.45
		Max	8.2	7.0	8.1	8.2	9.5
	Day 8	n	12	12	12	36	120
		Mean (SD)	5.48 (1.03)	4.93 (0.91)	5.88 (2.23)	5.43 (1.52)	5.39 (1.37)
		Min	4.0	3.1	3.6	3.1	3.1
		Median	5.55	5.00	5.40	5.35	5.20
		Max	7.2	6.5	11.1	11.1	11.1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Leukocytes (Blood) [10^9/L]	Day 29	n	12	12	12	36	117
		Mean (SD)	5.72 (1.41)	4.46 (0.89)	5.31 (1.10)	5.16 (1.24)	5.59 (1.59)
		Min	3.9	3.0	3.4	3.0	2.9
		Median	5.65	4.30	5.30	5.15	5.40
		Max	8.3	5.9	6.7	8.3	13.4
	Day 50	n	12	0	0	12	94
		Mean (SD)	5.39 (1.04)	- (-)	- (-)	5.39 (1.04)	5.63 (1.36)
		Min	3.8	-	-	3.8	3.4
		Median	5.35	-	-	5.35	5.40
		Max	7.4	-	-	7.4	11.9
Lymphocytes (Blood) [10^9/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	1.764 (0.428)	1.654 (0.437)	1.663 (0.403)	1.694 (0.414)	1.825 (0.474)
		Min	0.83	1.05	0.96	0.83	0.83
		Median	1.780	1.760	1.710	1.735	1.820
		Max	2.35	2.35	2.52	2.52	3.22

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Lymphocytes (Blood) [10^9/L]	Day 1	n	11	10	12	33	117
		Mean (SD)	1.761 (0.411)	1.532 (0.515)	1.693 (0.375)	1.667 (0.430)	1.751 (0.447)
		Min	0.76	0.68	1.32	0.68	0.68
		Median	1.820	1.410	1.630	1.690	1.710
		Max	2.20	2.38	2.57	2.57	2.86
	Day 2	n	12	12	12	36	120
		Mean (SD)	1.026 (0.316)	0.869 (0.294)	0.773 (0.204)	0.889 (0.288)	1.004 (0.405)
		Min	0.61	0.47	0.47	0.47	0.40
		Median	1.000	0.860	0.750	0.850	0.935
		Max	1.67	1.41	1.14	1.67	2.26
	Day 8	n	12	12	12	36	120
		Mean (SD)	1.748 (0.414)	1.521 (0.443)	1.863 (0.490)	1.711 (0.460)	1.796 (0.495)
		Min	0.92	0.70	1.14	0.70	0.70
		Median	1.665	1.550	1.760	1.630	1.725
		Max	2.49	2.25	2.79	2.79	3.71

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Lymphocytes (Blood) [10^9/L]	Day 29	n	12	11	12	35	114
		Mean (SD)	1.959 (0.497)	1.541 (0.474)	1.884 (0.471)	1.802 (0.501)	1.931 (0.561)
		Min	0.93	0.59	1.12	0.59	0.59
		Median	1.965	1.660	1.865	1.830	1.900
		Max	2.77	2.42	2.70	2.77	4.33
	Day 50	n	12	0	0	12	94
		Mean (SD)	1.798 (0.456)	- (-)	- (-)	1.798 (0.456)	1.841 (0.476)
		Min	0.96	-	-	0.96	0.87
		Median	1.780	-	-	1.780	1.800
		Max	2.55	-	-	2.55	3.29
Lymphocytes (Blood Smear) [10^9/L]	Day 1	n	0	2	0	2	2
		Mean (SD)	- (-)	1.85 (-)	- (-)	1.85 (-)	1.85 (-)
		Min	-	1.5	-	1.5	1.5
		Median	-	1.85	-	1.85	1.85
		Max	-	2.2	-	2.2	2.2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Lymphocytes (Blood Smear) [10^9/L]	Day 29	n	0	1	0	1	3
		Mean (SD)	- (-)	1.50 (-)	- (-)	1.50 (-)	1.87 (0.32)
		Min	-	1.5	-	1.5	1.5
		Median	-	1.50	-	1.50	2.00
		Max	-	1.5	-	1.5	2.1
Lymphocytes/Leukocytes (Blood) [%]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	27.34 (7.58)	29.98 (4.53)	26.49 (5.09)	27.94 (5.91)	30.01 (7.00)
		Min	18.1	23.8	21.2	18.1	12.7
		Median	26.90	29.65	24.15	26.90	29.55
		Max	46.0	37.9	36.3	46.0	46.0
	Day 1	n	11	10	12	33	117
		Mean (SD)	29.80 (6.27)	28.50 (6.19)	29.17 (7.73)	29.18 (6.62)	30.69 (6.85)
		Min	18.6	20.7	17.9	17.9	12.5
		Median	29.70	26.60	27.45	28.10	30.20
		Max	42.6	39.0	43.5	43.5	49.9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Lymphocytes/Leukocytes (Blood) [%]	Day 2	n	12	12	12	36	120
		Mean (SD)	19.20 (4.59)	16.35 (4.22)	14.15 (3.80)	16.57 (4.60)	17.93 (6.79)
		Min	11.7	9.7	8.7	8.7	7.5
		Median	18.75	17.70	15.30	17.05	17.45
		Max	28.0	22.0	20.0	28.0	40.3
	Day 8	n	12	12	12	36	120
		Mean (SD)	32.37 (8.11)	30.86 (6.98)	33.99 (10.86)	32.41 (8.64)	34.05 (7.98)
		Min	22.9	15.7	20.3	15.7	15.7
		Median	30.40	31.00	33.65	31.40	33.15
		Max	52.8	41.9	56.9	56.9	56.9
	Day 29	n	12	11	12	35	114
		Mean (SD)	34.74 (7.68)	34.13 (7.49)	36.14 (8.98)	35.03 (7.90)	34.98 (7.76)
		Min	22.7	19.5	21.4	19.5	13.7
		Median	32.50	33.90	34.00	33.70	34.40
		Max	47.9	43.6	54.2	54.2	54.2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Lymphocytes/Leukocytes (Blood) [%]	Day 50	n	12	0	0	12	94
		Mean (SD)	33.68 (8.33)	- (-)	- (-)	33.68 (8.33)	33.35 (7.42)
		Min	24.1	-	-	24.1	15.2
		Median	33.35	-	-	33.35	34.50
		Max	53.6	-	-	53.6	53.6
Lymphocytes/Leukocytes (Blood Smear) [%]	Day 1	n	0	2	0	2	2
		Mean (SD)	- (-)	35.0 (-)	- (-)	35.0 (-)	35.0 (-)
		Min	-	30	-	30	30
		Median	-	35.0	-	35.0	35.0
		Max	-	40	-	40	40
	Day 29	n	0	1	0	1	3
		Mean (SD)	- (-)	34.0 (-)	- (-)	34.0 (-)	43.3 (8.6)
		Min	-	34	-	34	34
		Median	-	34.0	-	34.0	45.0
		Max	-	34	-	34	51

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Monocytes (Blood) [10^9/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	0.603 (0.138)	0.462 (0.110)	0.496 (0.083)	0.520 (0.125)	0.514 (0.132)
		Min	0.39	0.28	0.36	0.28	0.24
		Median	0.585	0.470	0.495	0.510	0.500
		Max	0.84	0.62	0.68	0.84	0.86
	Day 1	n	11	10	12	33	117
		Mean (SD)	0.580 (0.118)	0.465 (0.124)	0.501 (0.120)	0.516 (0.126)	0.501 (0.123)
		Min	0.43	0.31	0.34	0.31	0.27
		Median	0.540	0.450	0.490	0.510	0.500
		Max	0.76	0.63	0.79	0.79	0.80
	Day 2	n	12	12	12	36	120
		Mean (SD)	0.670 (0.136)	0.610 (0.171)	0.668 (0.171)	0.649 (0.158)	0.648 (0.177)
		Min	0.49	0.37	0.47	0.37	0.34
		Median	0.630	0.620	0.605	0.620	0.640
		Max	0.91	0.96	1.06	1.06	1.12

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Monocytes (Blood) [10^9/L]	Day 8	n	12	12	12	36	120
		Mean (SD)	0.501 (0.095)	0.375 (0.086)	0.433 (0.138)	0.436 (0.118)	0.433 (0.119)
		Min	0.37	0.24	0.19	0.19	0.19
		Median	0.465	0.375	0.415	0.415	0.410
		Max	0.65	0.55	0.65	0.65	0.82
	Day 29	n	12	11	12	35	114
		Mean (SD)	0.508 (0.123)	0.365 (0.103)	0.428 (0.109)	0.436 (0.124)	0.475 (0.127)
		Min	0.39	0.24	0.26	0.24	0.24
		Median	0.465	0.340	0.425	0.410	0.465
		Max	0.77	0.60	0.59	0.77	0.78
	Day 50	n	12	0	0	12	94
		Mean (SD)	0.563 (0.093)	- (-)	- (-)	0.563 (0.093)	0.496 (0.122)
		Min	0.42	-	-	0.42	0.28
		Median	0.540	-	-	0.540	0.480
		Max	0.70	-	-	0.70	0.78

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Monocytes (Blood Smear) [10^9/L]	Day 1	n	0	2	0	2	2
		Mean (SD)	- (-)	0.260 (-)	- (-)	0.260 (-)	0.260 (-)
		Min	-	0.20	-	0.20	0.20
		Median	-	0.260	-	0.260	0.260
		Max	-	0.32	-	0.32	0.32
	Day 29	n	0	1	0	1	3
		Mean (SD)	- (-)	0.090 (-)	- (-)	0.090 (-)	0.160 (0.062)
		Min	-	0.09	-	0.09	0.09
		Median	-	0.090	-	0.090	0.180
		Max	-	0.09	-	0.09	0.21
Monocytes/Leukocytes (Blood) [%]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	9.40 (2.28)	8.53 (2.10)	8.00 (1.46)	8.64 (2.01)	8.43 (1.86)
		Min	5.1	6.5	5.6	5.1	4.2
		Median	9.60	7.90	7.95	8.15	8.35
		Max	13.1	12.4	10.3	13.1	14.2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Monocytes/Leukocytes (Blood) [%]	Day 1	n	11	10	12	33	117
		Mean (SD)	9.88 (1.52)	8.92 (2.23)	8.47 (1.54)	9.08 (1.82)	8.77 (1.87)
		Min	6.8	6.0	5.1	5.1	4.9
		Median	10.20	9.45	8.60	9.30	8.80
		Max	11.8	12.6	10.4	12.6	14.7
	Day 2	n	12	12	12	36	120
		Mean (SD)	12.88 (2.92)	11.58 (2.75)	11.98 (1.97)	12.14 (2.56)	11.64 (3.09)
		Min	7.0	7.4	9.1	7.0	6.9
		Median	12.80	11.40	11.80	12.15	11.30
		Max	17.7	16.3	15.2	17.7	20.7
	Day 8	n	12	12	12	36	120
		Mean (SD)	9.36 (1.96)	7.83 (1.98)	7.57 (1.71)	8.25 (2.00)	8.18 (1.82)
		Min	6.6	3.7	5.3	3.7	3.7
		Median	9.35	7.55	7.75	8.00	8.05
		Max	11.9	10.4	10.3	11.9	13.8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Monocytes/Leukocytes (Blood) [%]	Day 29	n	12	11	12	35	114
		Mean (SD)	9.13 (1.97)	8.18 (1.28)	8.06 (1.19)	8.46 (1.56)	8.62 (1.73)
		Min	6.1	6.8	5.8	5.8	4.6
		Median	9.90	7.60	8.65	8.70	8.65
		Max	12.0	10.1	9.2	12.0	15.2
	Day 50	n	12	0	0	12	94
		Mean (SD)	10.65 (2.07)	- (-)	- (-)	10.65 (2.07)	9.02 (2.10)
		Min	8.2	-	-	8.2	4.6
		Median	10.15	-	-	10.15	8.85
		Max	14.9	-	-	14.9	14.9
Monocytes/Leukocytes (Blood Smear) [%]	Day 1	n	0	2	0	2	2
		Mean (SD)	- (-)	5.0 (-)	- (-)	5.0 (-)	5.0 (-)
		Min	-	4	-	4	4
		Median	-	5.0	-	5.0	5.0
		Max	-	6	-	6	6

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Monocytes/Leukocytes (Blood Smear) [%]	Day 29	n	0	1	0	1	3
		Mean (SD)	- (-)	2.0 (-)	- (-)	2.0 (-)	3.7 (1.5)
		Min	-	2	-	2	2
		Median	-	2.0	-	2.0	4.0
		Max	-	2	-	2	5
Neutrophils (Blood) [10^9/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	3.978 (1.079)	3.189 (0.913)	3.954 (0.900)	3.707 (1.010)	3.617 (1.078)
		Min	2.03	1.76	2.49	1.76	1.76
		Median	3.925	3.175	3.995	3.620	3.515
		Max	5.98	4.73	5.09	5.98	7.22
	Day 1	n	11	10	12	33	117
		Mean (SD)	3.376 (0.859)	3.058 (0.635)	3.528 (1.016)	3.335 (0.859)	3.340 (1.073)
		Min	2.03	2.01	1.76	1.76	1.64
		Median	3.530	3.190	3.410	3.390	3.200
		Max	4.88	3.89	5.54	5.54	7.63

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Neutrophils (Blood) [10^9/L]	Day 2	n	12	12	12	36	120
		Mean (SD)	3.479 (0.925)	3.643 (0.752)	4.070 (1.197)	3.731 (0.980)	3.885 (1.116)
		Min	2.29	2.61	1.94	1.94	1.49
		Median	3.310	3.590	4.235	3.535	3.635
		Max	5.32	5.15	5.96	5.96	6.96
	Day 8	n	12	12	12	36	120
		Mean (SD)	3.010 (0.850)	2.831 (0.863)	3.330 (1.891)	3.057 (1.276)	2.945 (1.064)
		Min	1.32	1.88	1.38	1.32	1.11
		Median	3.305	2.770	2.825	2.925	2.745
		Max	4.38	5.19	7.85	7.85	7.85
	Day 29	n	12	11	12	35	114
		Mean (SD)	2.989 (1.017)	2.310 (0.498)	2.755 (0.866)	2.695 (0.854)	2.976 (1.181)
		Min	1.53	1.59	1.53	1.53	1.13
		Median	2.800	2.160	2.780	2.600	2.695
		Max	4.81	3.28	4.31	4.81	9.18

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Neutrophils (Blood) [10^9/L]	Day 50	n	12	0	0	12	94
		Mean (SD)	2.813 (0.780)	- (-)	- (-)	2.813 (0.780)	3.044 (1.045)
		Min	1.23	-	-	1.23	1.23
		Median	3.030	-	-	3.030	2.900
		Max	3.75	-	-	3.75	7.26
Neutrophils (Blood Smear) [10^9/L]	Day 1	n	0	2	0	2	2
		Mean (SD)	- (-)	2.45 (-)	- (-)	2.45 (-)	2.45 (-)
		Min	-	2.2	-	2.2	2.2
		Median	-	2.45	-	2.45	2.45
		Max	-	2.7	-	2.7	2.7
	Day 29	n	0	1	0	1	3
		Mean (SD)	- (-)	2.60 (-)	- (-)	2.60 (-)	1.70 (0.78)
		Min	-	2.6	-	2.6	1.2
		Median	-	2.60	-	2.60	1.30
		Max	-	2.6	-	2.6	2.6

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Neutrophils/Leukocytes (Blood) [%]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	60.11 (8.20)	57.20 (5.93)	62.38 (5.59)	59.89 (6.83)	57.93 (7.86)
		Min	41.4	46.0	48.9	41.4	38.6
		Median	60.75	57.00	63.60	60.75	58.55
		Max	73.9	66.6	69.4	73.9	81.8
	Day 1	n	11	10	12	33	117
		Mean (SD)	56.50 (6.71)	58.04 (6.98)	58.43 (8.58)	57.67 (7.34)	56.71 (7.57)
		Min	43.1	48.2	40.1	40.1	39.3
		Median	56.80	56.80	58.50	57.80	56.70
		Max	64.8	68.1	70.1	70.1	77.0
	Day 2	n	12	12	12	36	120
		Mean (SD)	64.50 (5.51)	68.65 (4.98)	71.07 (4.46)	68.07 (5.58)	67.55 (7.50)
		Min	54.2	57.6	62.6	54.2	41.3
		Median	65.10	69.50	71.50	68.95	68.20
		Max	73.1	75.4	77.4	77.4	82.1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Neutrophils/Leukocytes (Blood) [%]	Day 8	n	12	12	12	36	120
		Mean (SD)	54.18 (8.53)	56.99 (9.48)	54.03 (11.01)	55.07 (9.55)	53.82 (8.48)
		Min	33.1	43.9	32.8	32.8	32.8
		Median	57.45	55.65	56.35	57.20	54.00
		Max	61.9	79.8	70.7	79.8	79.8
	Day 29	n	12	11	12	35	114
		Mean (SD)	51.49 (7.88)	52.15 (7.75)	51.30 (8.89)	51.63 (7.97)	52.06 (8.49)
		Min	38.2	38.2	35.5	35.5	35.4
		Median	53.30	51.40	52.10	52.10	51.80
		Max	60.4	63.8	67.3	67.3	74.4
	Day 50	n	12	0	0	12	94
		Mean (SD)	51.59 (8.74)	- (-)	- (-)	51.59 (8.74)	53.31 (8.38)
		Min	32.4	-	-	32.4	32.4
		Median	53.70	-	-	53.70	52.15
		Max	62.0	-	-	62.0	72.3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Neutrophils/Leukocytes (Blood Smear) [%]	Day 1	n	0	2	0	2	2
		Mean (SD)	- (-)	47.0 (-)	- (-)	47.0 (-)	47.0 (-)
		Min	-	40	-	40	40
		Median	-	47.0	-	47.0	47.0
		Max	-	54	-	54	54
	Day 29	n	0	1	0	1	3
		Mean (SD)	- (-)	60.0 (-)	- (-)	60.0 (-)	39.3 (17.9)
		Min	-	60	-	60	29
		Median	-	60.0	-	60.0	29.0
		Max	-	60	-	60	60
Platelets [10^9/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	217.7 (42.9)	250.1 (46.3)	237.0 (55.0)	234.9 (48.8)	246.7 (44.8)
		Min	140	186	157	140	140
		Median	206.5	244.0	240.0	235.5	246.0
		Max	281	351	355	355	368

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Platelets [10^9/L]	Day 1	n	11	12	12	35	119
		Mean (SD)	222.5 (55.5)	242.3 (50.8)	244.2 (56.3)	236.7 (53.5)	239.4 (46.1)
		Min	133	186	185	133	133
		Median	209.0	251.0	244.5	244.0	243.0
		Max	313	371	390	390	390
	Day 2	n	12	12	12	36	120
		Mean (SD)	197.2 (50.9)	224.7 (38.6)	216.9 (52.7)	212.9 (47.9)	219.6 (43.2)
		Min	119	183	171	119	119
		Median	196.5	229.0	209.5	209.5	215.5
		Max	301	303	370	370	370
	Day 8	n	12	12	12	36	120
		Mean (SD)	224.3 (57.1)	244.1 (45.7)	237.4 (58.8)	235.3 (53.2)	242.6 (47.1)
		Min	135	188	168	135	135
		Median	230.5	245.0	238.0	231.0	235.0
		Max	320	322	382	382	390

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-1: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Platelets [10^9/L]	Day 29	n	12	12	12	36	117
		Mean (SD)	223.8 (51.9)	242.3 (53.6)	224.8 (59.6)	230.3 (54.2)	236.0 (51.6)
		Min	154	168	149	149	103
		Median	223.0	249.0	226.0	230.0	232.0
		Max	311	345	366	366	428
	Day 50	n	12	0	0	12	94
		Mean (SD)	223.9 (58.3)	- (-)	- (-)	223.9 (58.3)	239.2 (45.2)
		Min	129	-	-	129	129
		Median	220.0	-	-	220.0	236.5
		Max	310	-	-	310	351

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

Program: Tfsaf_LB_2_1.sas (Page 74 of 74)

Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Alanine Aminotransferase [U/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	20.33 (8.51)	18.83 (9.60)	24.00 (11.69)	20.50 (6.17)	24.75 (9.76)	21.42 (13.12)	23.08 (8.08)	21.85 (9.65)
		Min	11.0	10.0	11.0	12.0	12.0	7.0	8.0	7.0
		Median	18.00	15.50	19.50	18.50	23.50	15.50	25.50	19.00
		Max	40.0	41.0	47.0	32.0	45.0	44.0	36.0	47.0
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	18.67 (7.94)	16.58 (7.91)	21.08 (9.04)	18.25 (4.73)	21.33 (12.48)	19.13 (12.48)	23.92 (9.87)	19.85 (9.47)
		Min	8.0	8.0	9.0	13.0	10.0	2.5	11.0	2.5
		Median	16.50	14.50	19.00	17.00	18.50	17.50	23.00	18.00
		Max	33.0	37.0	36.0	26.0	48.0	47.0	42.0	48.0
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	17.17 (7.08)	17.42 (8.20)	20.08 (9.74)	17.92 (5.14)	19.33 (11.06)	17.79 (11.18)	22.58 (7.83)	18.90 (8.70)
		Min	8.0	8.0	8.0	11.0	7.0	2.5	13.0	2.5
		Median	15.00	14.50	16.50	17.50	17.00	15.50	21.50	16.00
		Max	29.0	38.0	38.0	28.0	44.0	40.0	36.0	44.0

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

Program: Tfsaf_LB_2_1.sas (Page 1 of 66)

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Alanine Aminotransferase [U/L]	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	16.67 (8.02)	18.42 (10.03)	19.92 (11.92)	20.67 (6.83)	19.92 (14.21)	21.17 (9.15)	23.33 (9.02)	20.01 (9.97)
		Min	7.0	8.0	9.0	13.0	6.0	9.0	13.0	6.0
		Median	14.00	15.50	15.50	18.00	16.00	17.50	22.00	17.00
		Max	33.0	44.0	43.0	38.0	55.0	39.0	48.0	55.0
	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	18.50 (7.86)	23.42 (12.88)	22.00 (8.96)	22.64 (9.16)	19.58 (9.66)	41.09 (34.56)	21.25 (9.28)	23.90 (16.60)
		Min	6.0	12.0	12.0	11.0	8.0	13.0	10.0	6.0
		Median	19.00	17.00	20.00	19.00	18.50	26.00	19.00	19.00
		Max	34.0	53.0	39.0	38.0	37.0	117.0	45.0	117.0
	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	16.45 (8.66)	18.67 (9.05)	18.82 (8.82)	18.67 (5.09)	17.92 (8.77)	19.08 (11.48)	19.00 (6.45)	18.39 (8.26)
		Min	8.0	7.0	7.0	12.0	9.0	6.0	10.0	6.0
		Median	12.00	15.00	17.00	18.00	15.00	15.00	19.00	17.00
		Max	31.0	39.0	38.0	32.0	37.0	47.0	31.0	47.0

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

Program: Tfsaf_LB_2_1.sas (Page 2 of 66)

Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Albumin [g/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	45.2 (2.4)	46.2 (3.1)	46.0 (2.5)	46.0 (3.6)	47.1 (1.8)	47.3 (2.2)	47.0 (2.4)	46.4 (2.6)
		Min	39	42	43	39	44	44	43	39
		Median	46.0	46.0	45.0	46.0	47.5	47.5	47.0	46.0
		Max	48	51	52	52	50	50	51	52
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	45.2 (2.6)	43.5 (3.3)	43.3 (3.4)	45.6 (2.2)	45.8 (1.6)	46.6 (2.3)	44.3 (3.1)	44.9 (2.8)
		Min	40	38	39	42	43	42	37	37
		Median	45.5	44.5	42.5	46.0	45.5	47.5	45.0	45.0
		Max	49	48	50	50	48	49	48	50
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	43.7 (3.4)	43.8 (3.3)	42.9 (2.3)	43.9 (2.6)	45.4 (1.8)	44.8 (1.1)	44.3 (2.6)	44.1 (2.6)
		Min	35	36	38	40	43	43	40	35
		Median	44.5	44.5	43.0	43.5	45.0	45.0	44.0	44.0
		Max	47	48	46	47	48	46	47	48

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Albumin [g/L]	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	44.8 (2.7)	44.3 (4.0)	44.3 (2.7)	44.8 (1.9)	44.0 (3.0)	44.3 (1.4)	44.9 (2.7)	44.5 (2.7)
		Min	38	38	41	42	39	42	40	38
		Median	44.5	45.0	43.0	44.0	44.0	44.5	45.0	44.0
		Max	49	50	49	48	49	46	50	50
	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	44.3 (2.4)	44.7 (3.3)	44.3 (2.9)	45.2 (2.0)	44.9 (1.7)	45.1 (2.2)	43.4 (2.8)	44.5 (2.5)
		Min	40	41	39	42	43	43	38	38
		Median	44.0	45.5	44.0	45.0	44.5	44.0	44.0	44.0
		Max	48	50	50	48	49	50	48	50
	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	42.0 (2.9)	46.3 (3.4)	43.0 (3.3)	45.3 (2.4)	43.3 (2.1)	45.8 (1.8)	44.1 (2.8)	44.3 (3.0)
		Min	36	38	38	42	39	44	38	36
		Median	42.0	46.5	42.0	45.0	44.0	45.5	44.0	44.5
		Max	45	51	48	49	46	50	48	51

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Alkaline Phosphatase [U/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	61.00 (20.87)	67.17 (22.15)	69.75 (22.22)	68.00 (10.75)	62.42 (15.72)	61.33 (19.12)	66.50 (14.91)	65.17 (18.03)
		Min	39.0	40.0	37.0	50.0	43.0	40.0	49.0	37.0
		Median	56.00	64.50	64.50	67.00	61.50	61.00	62.00	62.50
		Max	113.0	115.0	109.0	85.0	102.0	106.0	100.0	115.0
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	61.75 (24.00)	62.67 (21.58)	61.63 (26.90)	65.75 (9.28)	60.08 (15.97)	59.67 (17.80)	62.67 (10.59)	62.03 (18.43)
		Min	36.0	36.0	2.5	50.0	39.0	39.0	46.0	2.5
		Median	56.50	57.00	58.50	67.00	58.00	60.00	63.50	60.50
		Max	121.0	112.0	105.0	78.0	88.0	97.0	78.0	121.0
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	60.67 (24.82)	66.75 (21.64)	65.75 (21.34)	68.58 (11.44)	61.83 (15.22)	59.33 (16.12)	60.58 (9.45)	63.36 (17.60)
		Min	38.0	45.0	35.0	49.0	40.0	40.0	47.0	35.0
		Median	55.00	60.00	61.50	70.00	59.50	58.50	61.50	61.00
		Max	129.0	115.0	106.0	85.0	92.0	89.0	74.0	129.0

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

Program: Tfsaf_LB_2_1.sas (Page 5 of 66)

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Alkaline Phosphatase [U/L]	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	61.92 (22.85)	64.08 (19.75)	64.83 (20.56)	65.75 (10.80)	59.08 (11.03)	55.25 (15.05)	59.33 (10.53)	61.46 (16.30)
		Min	37.0	44.0	37.0	50.0	39.0	36.0	45.0	36.0
		Median	59.50	60.00	60.50	65.50	62.50	53.00	58.00	60.50
		Max	125.0	113.0	106.0	84.0	73.0	79.0	86.0	125.0
	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	63.67 (25.34)	68.92 (23.90)	62.64 (21.53)	63.82 (9.60)	61.33 (15.04)	56.36 (14.83)	60.92 (8.68)	62.58 (17.82)
		Min	37.0	41.0	33.0	49.0	42.0	37.0	47.0	33.0
		Median	57.50	68.50	59.00	65.00	60.50	52.00	61.50	61.00
		Max	122.0	125.0	99.0	76.0	95.0	77.0	79.0	125.0
	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	64.27 (25.25)	68.08 (21.52)	64.73 (21.78)	66.42 (11.92)	64.00 (17.97)	62.33 (14.88)	61.33 (9.57)	64.45 (17.62)
		Min	40.0	42.0	33.0	48.0	41.0	39.0	46.0	33.0
		Median	56.00	68.00	57.00	68.00	65.50	62.00	62.00	62.00
		Max	129.0	113.0	104.0	90.0	99.0	83.0	76.0	129.0

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

Program: Tfsaf_LB_2_1.sas (Page 6 of 66)

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Amylase [U/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	68.6 (11.9)	53.1 (14.3)	67.3 (23.3)	68.8 (19.5)	54.8 (16.7)	64.9 (19.6)	72.5 (16.1)	64.3 (18.4)
		Min	43	39	28	36	19	37	42	19
		Median	71.0	48.5	64.5	65.5	52.5	63.5	70.5	63.0
		Max	89	90	102	101	80	108	99	108
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	65.2 (18.0)	50.8 (13.7)	64.3 (25.7)	63.9 (18.2)	56.7 (21.1)	69.2 (30.2)	66.6 (15.1)	62.4 (21.1)
		Min	38	39	26	40	23	34	37	23
		Median	62.5	46.0	63.0	55.5	56.0	64.0	68.5	60.0
		Max	96	84	109	95	105	144	90	144
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	67.6 (13.3)	53.8 (13.7)	65.2 (27.6)	62.8 (15.9)	55.2 (20.1)	60.4 (20.0)	60.7 (13.6)	60.8 (18.3)
		Min	43	37	25	39	22	33	36	22
		Median	69.5	50.5	65.0	58.5	55.5	56.5	61.5	59.5
		Max	88	83	114	88	101	111	83	114

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Amylase [U/L]	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	65.7 (19.0)	54.0 (11.0)	68.3 (30.9)	65.6 (20.9)	56.9 (21.7)	62.4 (23.6)	68.8 (18.9)	63.1 (21.4)
		Min	39	41	27	36	24	31	32	24
		Median	63.0	52.0	61.5	67.5	61.0	55.5	69.0	60.5
		Max	104	74	129	101	106	109	98	129
	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	69.1 (16.1)	51.3 (12.4)	63.8 (20.0)	61.4 (17.4)	57.6 (23.0)	66.4 (17.6)	75.4 (42.7)	63.6 (23.7)
		Min	40	33	33	31	23	37	36	23
		Median	67.0	49.0	61.0	58.0	56.0	68.0	66.5	61.0
		Max	99	77	96	94	118	98	204	204
	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	65.5 (12.8)	51.8 (9.3)	66.9 (22.3)	64.3 (13.6)	55.8 (19.2)	60.1 (20.0)	68.1 (19.1)	61.7 (17.5)
		Min	41	41	26	34	22	30	35	22
		Median	70.0	49.0	65.0	64.5	53.5	60.5	68.5	62.0
		Max	84	71	98	82	88	103	101	103

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

Program: Tfsaf_LB_2_1.sas (Page 8 of 66)

Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Aspartate Aminotransferase [U/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	19.00 (5.94)	20.33 (4.85)	20.67 (5.45)	23.25 (5.46)	23.83 (7.74)	20.50 (6.91)	23.08 (4.40)	21.52 (5.95)
		Min	11.0	14.0	14.0	15.0	15.0	11.0	13.0	11.0
		Median	19.00	20.00	20.00	22.50	21.00	20.00	22.50	21.00
		Max	34.0	30.0	32.0	36.0	41.0	37.0	30.0	41.0
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	21.75 (12.14)	17.75 (3.79)	19.08 (5.16)	21.00 (4.63)	20.58 (6.42)	22.17 (7.47)	20.67 (4.36)	20.43 (6.72)
		Min	11.0	13.0	14.0	15.0	13.0	14.0	14.0	11.0
		Median	19.00	18.00	18.50	20.00	20.00	20.50	21.00	19.00
		Max	59.0	26.0	33.0	28.0	33.0	42.0	27.0	59.0
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	16.88 (8.07)	17.50 (3.55)	18.33 (4.72)	19.25 (4.65)	19.17 (4.57)	20.33 (6.14)	18.92 (3.60)	18.63 (5.18)
		Min	2.5	13.0	13.0	13.0	13.0	15.0	13.0	2.5
		Median	17.00	18.00	17.50	17.50	18.50	18.50	18.00	18.00
		Max	36.0	24.0	30.0	28.0	25.0	38.0	24.0	38.0

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Aspartate Aminotransferase [U/L]	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	20.08 (5.05)	20.00 (5.13)	18.42 (3.55)	21.83 (3.56)	21.67 (7.06)	18.33 (5.31)	20.25 (2.73)	20.08 (4.82)
		Min	12.0	13.0	14.0	17.0	14.0	14.0	15.0	12.0
		Median	20.00	18.50	17.50	22.00	22.00	17.50	20.50	19.50
		Max	30.0	32.0	24.0	28.0	39.0	33.0	24.0	39.0
	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	17.83 (3.66)	22.67 (6.20)	17.91 (3.39)	22.18 (5.64)	20.25 (5.17)	26.36 (10.55)	20.75 (3.93)	21.10 (6.30)
		Min	12.0	15.0	12.0	15.0	14.0	15.0	16.0	12.0
		Median	18.50	23.00	18.00	24.00	18.50	29.00	20.00	19.00
		Max	22.0	36.0	23.0	32.0	34.0	44.0	27.0	44.0
	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	18.82 (5.40)	22.33 (5.16)	18.55 (3.86)	20.83 (4.53)	20.00 (3.79)	20.67 (6.31)	21.42 (3.68)	20.41 (4.76)
		Min	12.0	16.0	14.0	15.0	16.0	11.0	16.0	11.0
		Median	19.00	23.00	17.00	20.50	19.50	20.00	21.00	20.00
		Max	28.0	35.0	27.0	32.0	26.0	35.0	29.0	35.0

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Bilirubin (Serum) [µmol/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	7.83 (3.69)	9.48 (3.95)	10.18 (8.37)	9.83 (4.95)	8.63 (2.86)	8.07 (1.55)	11.25 (5.58)	9.32 (4.82)
		Min	1.3	4.4	1.3	3.9	3.8	5.5	5.0	1.3
		Median	6.40	7.70	8.55	8.90	8.60	8.45	11.30	8.40
		Max	13.3	15.9	33.9	21.0	13.2	10.8	24.5	33.9
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	8.19 (3.43)	9.79 (4.85)	7.99 (5.42)	8.63 (3.62)	7.08 (1.61)	6.79 (2.03)	9.07 (5.37)	8.22 (4.00)
		Min	3.8	3.6	1.3	3.8	3.4	3.9	2.7	1.3
		Median	7.95	9.00	7.10	6.95	7.00	6.35	7.35	7.20
		Max	15.0	21.4	18.5	14.4	9.1	10.3	18.8	21.4
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	8.84 (3.65)	10.11 (5.06)	9.18 (5.30)	10.21 (5.45)	9.36 (3.03)	8.18 (2.17)	12.42 (7.70)	9.76 (4.91)
		Min	4.6	1.3	4.4	2.7	4.8	4.6	5.1	1.3
		Median	7.70	10.00	7.70	7.95	8.55	8.05	10.30	8.65
		Max	15.9	16.9	22.4	22.1	15.7	11.6	29.2	29.2

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Bilirubin (Serum) [µmol/L]	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	6.67 (3.16)	9.31 (4.76)	8.00 (4.66)	8.14 (3.29)	6.07 (3.66)	6.16 (2.34)	8.80 (3.66)	7.59 (3.79)
		Min	1.3	3.8	3.1	3.1	1.3	3.8	2.7	1.3
		Median	5.80	8.00	7.55	8.30	5.50	5.40	7.95	6.70
		Max	12.3	19.0	17.8	13.7	13.0	11.1	15.0	19.0
	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	7.37 (2.30)	8.91 (3.81)	6.30 (3.47)	9.66 (3.98)	6.35 (4.07)	6.11 (2.52)	13.30 (7.37)	8.32 (4.77)
		Min	2.7	4.8	2.7	1.3	1.3	3.4	3.9	1.3
		Median	7.45	7.65	5.60	9.70	5.55	5.30	12.00	6.80
		Max	12.3	18.5	14.5	15.9	14.5	12.7	29.1	29.1
	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	7.58 (3.90)	9.58 (5.65)	6.09 (3.52)	9.44 (5.23)	8.56 (4.72)	7.96 (3.03)	12.44 (8.31)	8.85 (5.34)
		Min	3.6	2.7	1.3	4.1	3.6	3.6	4.1	1.3
		Median	6.30	8.80	6.00	8.00	7.35	7.45	11.15	7.80
		Max	16.4	22.9	13.7	21.4	16.9	14.4	35.9	35.9

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
C Reactive Protein [mg/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.675 (0.473)	1.158 (1.294)	1.658 (1.969)	0.438 (0.600)	0.646 (0.452)	0.888 (1.143)	0.667 (0.528)	0.876 (1.094)
		Min	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15
		Median	0.650	0.400	0.700	0.150	0.550	0.450	0.500	0.500
		Max	1.90	3.50	6.10	1.80	1.60	4.00	2.00	6.10
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.833 (0.556)	0.638 (0.766)	1.033 (1.051)	0.558 (0.764)	0.871 (0.829)	0.850 (1.106)	0.679 (0.589)	0.780 (0.816)
		Min	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15
		Median	0.800	0.150	0.650	0.225	0.700	0.450	0.500	0.450
		Max	1.90	2.40	3.60	2.60	2.90	3.90	1.90	3.90
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.742 (0.487)	0.813 (0.854)	2.188 (2.421)	3.083 (1.628)	6.042 (5.924)	6.733 (6.200)	7.700 (4.637)	3.900 (4.594)
		Min	0.15	0.15	0.15	0.50	0.50	1.20	1.90	0.15
		Median	0.750	0.600	1.100	3.100	4.450	4.500	6.300	2.650
		Max	1.60	3.00	8.30	6.10	23.70	22.30	16.30	23.70

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
C Reactive Protein [mg/L]	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	0.625 (0.196)	1.063 (1.232)	1.208 (1.086)	0.642 (0.654)	0.988 (0.518)	1.342 (1.006)	1.325 (0.825)	1.027 (0.870)
		Min	0.40	0.15	0.15	0.15	0.15	0.50	0.60	0.15
		Median	0.600	0.550	0.700	0.400	0.950	1.000	1.000	0.800
		Max	1.00	4.20	3.80	2.00	2.10	3.90	3.10	4.20
	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	0.979 (0.682)	2.358 (2.167)	1.423 (1.254)	1.200 (1.333)	1.246 (0.769)	2.755 (1.980)	0.508 (0.379)	1.485 (1.502)
		Min	0.15	0.40	0.15	0.30	0.15	0.40	0.15	0.15
		Median	0.700	1.800	1.000	0.700	1.050	2.000	0.400	0.900
		Max	2.40	7.30	4.00	4.00	2.80	6.00	1.30	7.30
	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	0.832 (0.587)	1.192 (0.760)	0.964 (0.955)	0.858 (0.669)	0.729 (0.658)	0.846 (0.840)	0.342 (0.244)	0.821 (0.718)
		Min	0.15	0.50	0.15	0.30	0.15	0.15	0.15	0.15
		Median	0.800	1.050	0.800	0.600	0.500	0.550	0.275	0.600
		Max	2.00	2.90	3.50	2.30	2.10	2.70	0.80	3.50

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Calcium [mmol/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	2.359 (0.062)	2.413 (0.110)	2.428 (0.090)	2.399 (0.120)	2.418 (0.097)	2.426 (0.071)	2.383 (0.075)	2.404 (0.091)
		Min	2.26	2.29	2.28	2.20	2.22	2.32	2.25	2.20
		Median	2.360	2.395	2.420	2.405	2.430	2.420	2.390	2.400
		Max	2.45	2.67	2.60	2.60	2.65	2.54	2.50	2.67
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	2.360 (0.086)	2.371 (0.099)	2.186 (0.664)	2.360 (0.070)	2.397 (0.078)	2.418 (0.061)	2.321 (0.088)	2.345 (0.262)
		Min	2.24	2.23	0.10	2.20	2.24	2.27	2.14	0.10
		Median	2.350	2.335	2.360	2.355	2.410	2.410	2.345	2.365
		Max	2.57	2.55	2.58	2.47	2.51	2.49	2.45	2.58
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	2.329 (0.076)	2.364 (0.104)	2.349 (0.090)	2.334 (0.073)	2.360 (0.072)	2.343 (0.044)	2.301 (0.077)	2.340 (0.078)
		Min	2.21	2.17	2.21	2.21	2.24	2.27	2.18	2.17
		Median	2.320	2.380	2.340	2.340	2.355	2.345	2.330	2.340
		Max	2.47	2.50	2.56	2.45	2.50	2.43	2.39	2.56

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Calcium [mmol/L]	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	2.343 (0.068)	2.371 (0.122)	2.362 (0.114)	2.369 (0.074)	2.341 (0.102)	2.349 (0.060)	2.320 (0.080)	2.351 (0.090)
		Min	2.24	2.22	2.21	2.26	2.18	2.29	2.16	2.16
		Median	2.340	2.360	2.330	2.375	2.330	2.320	2.330	2.335
		Max	2.47	2.62	2.58	2.48	2.53	2.46	2.43	2.62
	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	2.378 (0.064)	2.389 (0.087)	2.390 (0.109)	2.339 (0.069)	2.368 (0.091)	2.365 (0.038)	2.337 (0.093)	2.367 (0.081)
		Min	2.22	2.27	2.25	2.24	2.28	2.30	2.18	2.18
		Median	2.390	2.390	2.370	2.330	2.325	2.370	2.360	2.370
		Max	2.44	2.52	2.64	2.44	2.53	2.43	2.45	2.64
	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	2.332 (0.050)	2.412 (0.107)	2.365 (0.129)	2.385 (0.079)	2.332 (0.102)	2.410 (0.079)	2.351 (0.086)	2.370 (0.095)
		Min	2.25	2.16	2.20	2.29	2.11	2.29	2.22	2.11
		Median	2.340	2.405	2.320	2.365	2.335	2.405	2.360	2.355
		Max	2.42	2.55	2.63	2.53	2.49	2.56	2.49	2.63

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Creatinine [µmol/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	73.733 (9.600)	70.717 (12.567)	68.150 (9.527)	77.783 (15.871)	75.658 (9.641)	63.363 (24.787)	68.954 (20.472)	71.194 (15.777)
		Min	56.60	50.40	56.60	53.00	54.80	8.85	8.85	8.85
		Median	76.450	70.700	69.400	81.750	79.550	66.300	72.500	71.600
		Max	86.60	88.40	90.20	109.60	84.90	89.30	88.40	109.60
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	72.708 (7.872)	71.542 (11.230)	67.900 (9.574)	80.950 (16.401)	73.667 (9.309)	73.900 (13.155)	73.533 (12.488)	73.457 (11.876)
		Min	59.20	48.60	53.00	55.70	53.90	61.90	51.30	48.60
		Median	76.900	71.600	67.600	82.650	76.450	68.550	71.600	72.950
		Max	83.10	84.90	86.60	111.40	85.70	100.80	91.10	111.40
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	76.250 (11.232)	70.733 (13.119)	66.000 (8.031)	80.450 (16.877)	75.508 (14.035)	80.067 (16.221)	77.067 (15.498)	75.154 (14.207)
		Min	54.80	48.60	53.90	53.00	49.50	60.10	56.60	48.60
		Median	79.150	70.300	65.400	81.800	78.700	74.700	75.150	74.300
		Max	94.60	91.10	84.90	105.20	97.20	105.20	106.10	106.10

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Creatinine [µmol/L]	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	79.925 (10.992)	69.333 (10.796)	70.350 (12.113)	74.908 (17.140)	73.533 (9.606)	74.542 (11.492)	76.392 (11.616)	74.140 (12.190)
		Min	60.10	50.40	50.40	46.00	54.80	58.30	53.00	46.00
		Median	80.000	68.950	70.700	80.000	72.950	71.150	75.150	73.400
		Max	97.20	87.50	96.40	97.20	88.40	92.80	94.60	97.20
	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	78.250 (10.965)	68.000 (11.008)	69.664 (14.328)	77.700 (15.637)	77.475 (10.331)	81.082 (11.098)	75.067 (12.696)	75.289 (12.705)
		Min	64.50	49.50	53.00	47.70	56.60	66.30	51.30	47.70
		Median	76.050	68.050	66.300	83.100	76.450	78.700	75.150	75.100
		Max	101.70	84.90	99.00	99.00	93.70	102.50	95.50	102.50
	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	83.082 (15.144)	70.725 (12.381)	71.991 (11.063)	77.567 (15.254)	75.283 (11.816)	76.242 (13.418)	76.983 (14.489)	75.944 (13.471)
		Min	64.50	53.00	54.80	48.60	53.90	58.30	52.20	48.60
		Median	83.100	69.850	69.800	81.750	76.900	72.950	73.350	75.100
		Max	122.00	96.40	90.20	98.10	100.80	96.40	107.00	122.00

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Ferritin [µg/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	77.83 (65.51)	118.05 (151.48)	90.38 (94.71)	79.51 (56.34)	91.03 (53.99)	90.99 (82.51)	100.68 (64.80)	92.64 (85.00)
		Min	6.4	4.7	8.7	10.5	28.3	13.5	36.8	4.7
		Median	63.40	57.50	54.35	79.30	78.10	49.90	92.95	72.65
		Max	211.1	484.5	328.2	222.5	210.6	248.5	271.7	484.5
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	87.77 (70.41)	100.47 (143.99)	80.89 (88.87)	71.78 (59.06)	79.23 (44.60)	90.72 (85.42)	103.31 (62.19)	87.74 (82.28)
		Min	7.2	4.9	9.1	12.2	24.6	11.4	34.4	4.9
		Median	58.60	48.85	50.75	59.20	70.45	48.40	90.85	59.30
		Max	214.9	460.8	322.3	235.7	156.7	264.3	254.8	460.8
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	81.83 (62.09)	108.14 (151.90)	84.88 (89.62)	74.34 (47.46)	91.32 (49.23)	96.76 (82.18)	111.08 (59.04)	92.62 (82.28)
		Min	8.7	4.5	9.4	12.3	28.8	16.9	46.0	4.5
		Median	63.15	53.95	53.50	65.35	82.00	58.30	103.00	65.70
		Max	190.3	483.8	323.8	199.0	168.1	267.8	245.8	483.8

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Ferritin [µg/L]	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	75.82 (60.50)	106.73 (159.44)	84.22 (92.65)	73.01 (59.45)	96.11 (67.12)	113.10 (91.67)	122.78 (82.10)	95.97 (91.55)
		Min	8.8	5.6	7.8	11.8	34.1	20.7	37.5	5.6
		Median	58.10	37.10	63.30	56.55	73.40	65.10	111.65	61.70
		Max	185.6	481.9	339.1	226.6	240.8	303.1	303.6	481.9
	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	80.53 (75.24)	113.73 (162.87)	97.99 (121.78)	79.48 (46.92)	86.53 (49.39)	124.25 (95.10)	91.21 (70.50)	96.09 (94.62)
		Min	7.4	4.3	8.2	31.6	29.8	20.0	22.2	4.3
		Median	58.40	47.45	65.20	59.30	72.95	84.40	62.95	66.10
		Max	257.9	491.5	427.6	183.9	189.7	303.1	254.6	491.5
	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	76.56 (67.41)	97.70 (152.65)	76.38 (101.05)	51.55 (41.31)	68.76 (46.06)	76.33 (72.69)	74.11 (56.10)	74.44 (82.55)
		Min	6.4	4.9	7.3	14.6	23.2	8.6	16.8	4.9
		Median	50.70	36.95	53.50	43.60	51.05	50.85	64.40	50.25
		Max	201.3	501.8	358.5	171.2	162.8	241.4	216.2	501.8

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Follicle Stimulating Hormone [IU/L]	Day -30 to 0	n	4	4	3	4	1	0	0	16
		Mean (SD)	20.38 (29.27)	39.70 (59.75)	99.47 (37.66)	12.80 (18.22)	2.20 (-)	- (-)	- (-)	37.01 (47.26)
		Min	3.4	3.8	64.9	1.9	2.2	-	-	1.9
		Median	6.95	13.20	93.90	4.65	2.20	-	-	7.05
		Max	64.2	128.6	139.6	40.0	2.2	-	-	139.6
Gamma Glutamyl Transferase [U/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	16.2 (5.6)	20.8 (10.4)	21.8 (13.3)	15.3 (7.0)	18.3 (6.6)	21.4 (20.3)	24.5 (21.5)	19.7 (13.4)
		Min	7	10	8	9	9	9	5	5
		Median	16.0	18.5	16.5	12.5	17.0	14.0	17.0	15.5
		Max	25	45	53	32	30	82	79	82
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	16.1 (5.7)	19.1 (10.5)	19.8 (12.1)	14.8 (5.8)	17.3 (6.0)	21.3 (19.7)	23.7 (22.8)	18.9 (13.3)
		Min	7	8	6	9	9	9	6	6
		Median	15.0	16.0	14.5	12.5	17.0	14.0	15.5	14.5
		Max	25	45	45	28	28	80	88	88

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Gamma Glutamyl Transferase [U/L]	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	15.6 (5.5)	19.1 (10.3)	19.3 (12.2)	14.3 (6.6)	16.7 (5.8)	20.8 (19.4)	23.3 (21.5)	18.4 (12.9)
		Min	8	9	6	8	8	9	6	6
		Median	14.5	16.5	14.0	11.5	16.5	13.5	14.5	14.0
		Max	25	42	48	27	26	78	83	83
	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	16.2 (5.5)	20.0 (11.2)	20.8 (14.4)	16.5 (10.3)	17.9 (6.1)	23.4 (20.5)	29.7 (41.4)	20.6 (19.2)
		Min	8	8	7	9	9	10	7	7
		Median	14.5	18.0	15.0	12.0	18.0	16.0	16.0	15.0
		Max	26	47	56	45	26	82	158	158
	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	17.1 (6.0)	23.4 (13.3)	22.9 (15.7)	18.6 (13.2)	19.8 (6.9)	30.5 (24.0)	21.4 (19.4)	21.9 (15.1)
		Min	8	8	7	9	10	11	5	5
		Median	15.5	22.5	15.0	13.0	19.5	23.0	15.5	16.0
		Max	30	54	51	50	30	90	77	90

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Gamma Glutamyl Transferase [U/L]	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	15.5 (5.9)	22.7 (11.3)	20.5 (13.8)	15.8 (8.6)	17.0 (5.8)	23.1 (20.8)	20.4 (22.0)	19.3 (13.9)
		Min	8	10	6	9	10	10	4	4
		Median	13.0	21.5	17.0	12.5	18.5	17.0	15.5	15.5
		Max	27	46	50	39	27	84	87	87
Glucose (Blood) [mmol/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	5.093 (0.351)	5.459 (0.629)	5.556 (0.579)	5.518 (0.431)	5.443 (0.421)	5.189 (0.411)	5.227 (0.393)	5.355 (0.483)
		Min	4.34	4.84	5.00	4.45	4.73	4.67	4.67	4.34
		Median	5.060	5.120	5.340	5.645	5.390	5.145	5.090	5.340
		Max	5.78	6.84	7.01	6.00	5.95	5.73	5.78	7.01
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	4.943 (0.330)	5.302 (0.709)	5.024 (0.548)	5.171 (0.536)	5.263 (0.402)	4.957 (0.478)	5.276 (0.371)	5.134 (0.500)
		Min	4.34	4.34	4.23	4.00	4.73	4.28	4.39	4.00
		Median	4.920	5.170	4.895	5.230	5.175	4.895	5.365	5.060
		Max	5.50	6.62	6.12	6.06	6.00	5.95	5.67	6.62

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Glucose (Blood) [mmol/L]	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	4.850 (0.637)	5.286 (0.842)	4.995 (0.696)	5.296 (0.446)	5.213 (0.392)	5.171 (0.305)	5.439 (0.426)	5.179 (0.574)
		Min	3.34	4.50	4.06	4.61	4.34	4.56	4.67	3.34
		Median	4.865	4.975	4.785	5.310	5.175	5.200	5.420	5.120
		Max	5.67	7.45	6.28	6.34	5.89	5.62	6.06	7.45
	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	5.125 (0.534)	5.213 (0.764)	5.010 (0.379)	5.455 (0.427)	5.290 (0.564)	5.148 (0.432)	5.130 (0.526)	5.196 (0.529)
		Min	4.28	4.28	4.45	4.95	4.50	4.56	4.28	4.28
		Median	5.145	5.145	4.950	5.335	5.335	5.090	5.090	5.170
		Max	5.89	7.12	5.62	6.51	6.17	5.84	6.28	7.12
	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	4.973 (0.445)	5.292 (0.624)	5.355 (0.652)	5.171 (0.458)	5.222 (0.587)	5.109 (0.342)	5.287 (0.616)	5.201 (0.538)
		Min	4.34	4.56	4.73	4.56	4.17	4.73	4.45	4.17
		Median	4.975	5.120	5.170	5.060	5.145	5.000	5.225	5.120
		Max	5.67	6.67	6.67	6.17	6.28	5.78	6.89	6.89

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Glucose (Blood) [mmol/L]	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	5.257 (0.535)	5.374 (0.772)	5.515 (0.734)	5.588 (0.878)	5.362 (0.577)	5.338 (0.466)	5.083 (0.447)	5.359 (0.643)
		Min	4.23	4.73	4.39	4.34	4.78	4.73	4.23	4.23
		Median	5.340	5.115	5.390	5.390	5.145	5.310	5.060	5.340
		Max	6.12	7.28	6.78	7.28	6.34	6.06	5.67	7.28
Lipase [U/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	34.6 (14.4)	28.7 (7.2)	28.1 (12.4)	32.8 (11.8)	32.5 (13.8)	38.8 (16.7)	33.2 (10.1)	32.6 (12.6)
		Min	20	16	17	14	17	16	19	14
		Median	30.5	30.5	26.5	31.5	26.5	35.0	33.0	30.0
		Max	73	42	62	52	69	74	51	74
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	31.7 (10.9)	28.1 (6.7)	28.2 (11.6)	31.8 (13.8)	33.1 (10.5)	55.1 (55.1)	36.2 (10.8)	34.9 (23.9)
		Min	24	19	16	14	18	14	24	14
		Median	27.0	28.0	26.0	29.0	32.0	36.5	36.5	29.0
		Max	62	39	60	60	51	218	55	218

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Lipase [U/L]	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	33.3 (12.3)	30.2 (9.2)	28.3 (13.8)	30.8 (11.8)	31.1 (12.6)	35.6 (17.0)	28.8 (9.7)	31.2 (12.3)
		Min	22	17	13	14	16	14	18	13
		Median	31.0	31.0	25.5	32.0	30.0	28.5	27.0	30.0
		Max	70	44	67	54	62	69	50	70
	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	33.4 (10.8)	31.0 (9.1)	30.5 (13.8)	33.3 (10.1)	36.1 (15.8)	39.0 (19.3)	37.6 (13.0)	34.4 (13.4)
		Min	18	16	18	15	16	14	20	14
		Median	32.0	32.0	27.0	30.0	33.5	34.0	35.5	32.5
		Max	53	52	69	48	72	85	64	85
	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	34.2 (12.7)	29.5 (7.5)	31.5 (14.8)	34.2 (22.3)	32.0 (12.3)	43.5 (17.4)	70.0 (141.9)	39.4 (55.9)
		Min	21	18	19	15	14	25	18	14
		Median	30.5	29.5	28.0	25.0	29.0	40.0	28.5	29.0
		Max	64	44	72	87	57	75	520	520

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Lipase [U/L]	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	34.1 (20.3)	30.8 (8.6)	30.9 (17.1)	33.9 (12.0)	36.9 (35.9)	35.1 (15.7)	32.8 (11.1)	33.5 (18.6)
		Min	18	17	19	15	14	11	19	11
		Median	31.0	31.5	26.0	36.5	27.5	32.0	30.5	30.0
		Max	93	44	79	50	149	66	52	149
Potassium [mmol/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	4.53 (0.31)	4.39 (0.22)	4.54 (0.36)	4.62 (0.41)	4.37 (0.34)	4.40 (0.42)	4.48 (0.19)	4.48 (0.33)
		Min	4.1	4.1	4.1	3.9	3.6	3.6	4.2	3.6
		Median	4.50	4.40	4.45	4.60	4.50	4.35	4.50	4.50
		Max	5.0	4.9	5.4	5.5	4.7	5.1	4.8	5.5
	Day 1	n	12	12	11	12	12	12	12	83
		Mean (SD)	4.69 (0.71)	4.45 (0.22)	4.54 (0.23)	4.54 (0.27)	4.54 (0.14)	4.50 (0.47)	4.43 (0.28)	4.53 (0.37)
		Min	4.1	4.1	4.2	4.1	4.3	3.7	4.0	3.7
		Median	4.45	4.45	4.60	4.50	4.55	4.45	4.45	4.50
		Max	6.7	4.9	4.9	5.0	4.7	5.4	4.8	6.7

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

Program: Tfsaf_LB_2_1.sas (Page 27 of 66)

Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Potassium [mmol/L]	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	4.65 (0.56)	4.36 (0.19)	4.73 (0.35)	4.26 (0.30)	4.45 (0.30)	4.31 (0.26)	4.03 (0.23)	4.40 (0.39)
		Min	4.2	4.0	4.1	3.7	4.0	3.9	3.7	3.7
		Median	4.45	4.40	4.80	4.20	4.40	4.25	4.00	4.30
		Max	6.2	4.7	5.3	4.7	5.1	4.8	4.5	6.2
	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	4.51 (0.42)	4.41 (0.19)	4.52 (0.32)	4.46 (0.30)	4.41 (0.22)	4.28 (0.26)	4.45 (0.34)	4.43 (0.30)
		Min	4.2	4.1	4.0	4.0	4.1	3.8	4.0	3.8
		Median	4.40	4.40	4.55	4.50	4.40	4.35	4.35	4.40
		Max	5.7	4.7	4.9	4.9	4.9	4.7	5.0	5.7
	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	4.38 (0.36)	4.38 (0.22)	4.75 (0.25)	4.34 (0.31)	4.43 (0.27)	4.35 (0.48)	4.43 (0.48)	4.43 (0.36)
		Min	3.7	4.1	4.2	3.9	4.0	3.4	3.6	3.4
		Median	4.35	4.30	4.80	4.30	4.45	4.30	4.35	4.40
		Max	5.0	4.8	5.1	5.0	4.8	5.1	5.3	5.3

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Potassium [mmol/L]	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	4.45 (0.44)	4.48 (0.37)	4.91 (0.48)	4.40 (0.36)	4.34 (0.22)	4.52 (0.44)	4.58 (0.38)	4.52 (0.41)
		Min	3.5	4.1	4.3	4.0	4.0	3.9	3.9	3.5
		Median	4.40	4.40	4.90	4.35	4.40	4.50	4.50	4.50
		Max	5.1	5.4	5.7	5.2	4.6	5.2	5.3	5.7
Sodium [mmol/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	139.8 (1.7)	139.8 (1.3)	140.9 (1.3)	139.2 (2.3)	139.7 (1.8)	139.4 (1.5)	139.3 (1.5)	139.7 (1.7)
		Min	137	138	139	135	136	136	137	135
		Median	140.0	139.5	141.0	139.5	140.0	139.5	139.0	140.0
		Max	143	142	143	143	142	142	141	143
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	139.3 (2.0)	140.9 (1.8)	140.0 (2.2)	139.7 (1.2)	139.3 (2.2)	139.6 (1.7)	139.7 (1.5)	139.8 (1.8)
		Min	135	138	135	138	134	136	138	134
		Median	139.5	140.0	140.0	139.5	139.5	140.0	139.0	140.0
		Max	142	144	143	142	143	142	142	144

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

Program: Tfsaf_LB_2_1.sas (Page 29 of 66)

Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Sodium [mmol/L]	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	140.1 (1.4)	140.3 (1.6)	140.1 (2.6)	138.0 (1.8)	138.8 (1.5)	137.5 (1.3)	138.3 (2.1)	139.0 (2.0)
		Min	138	137	135	135	137	136	135	135
		Median	140.0	141.0	140.0	138.0	139.0	137.0	138.5	139.0
		Max	142	142	144	142	141	140	141	144
	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	140.0 (0.9)	140.4 (1.5)	139.8 (2.5)	139.3 (1.1)	139.9 (1.6)	138.8 (1.4)	140.3 (1.0)	139.8 (1.6)
		Min	139	137	134	138	137	136	139	134
		Median	140.0	140.5	140.0	139.0	140.0	139.0	140.0	140.0
		Max	142	143	143	142	143	141	142	143
	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	139.8 (1.5)	140.6 (1.7)	139.3 (2.4)	139.1 (1.6)	140.4 (1.8)	140.3 (1.6)	139.6 (1.2)	139.9 (1.7)
		Min	137	138	135	136	137	137	138	135
		Median	140.0	140.0	139.0	139.0	140.5	141.0	139.5	140.0
		Max	142	144	143	142	143	142	141	144

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Sodium [mmol/L]	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	140.3 (2.1)	140.4 (1.4)	140.3 (2.3)	139.5 (1.7)	139.8 (0.8)	139.3 (1.7)	140.3 (1.6)	140.0 (1.7)
		Min	136	138	136	137	139	135	136	135
		Median	140.0	140.5	141.0	139.0	140.0	139.5	141.0	140.0
		Max	144	142	143	142	141	141	142	144
Urea Nitrogen [mmol/L]	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	4.837 (0.964)	4.508 (1.257)	4.105 (1.113)	4.279 (0.988)	4.652 (0.982)	4.583 (1.349)	4.083 (1.412)	4.435 (1.154)
		Min	3.82	3.00	2.18	2.82	3.18	2.32	1.82	1.82
		Median	4.340	4.320	4.090	4.430	4.500	4.840	3.910	4.265
		Max	6.82	6.75	6.18	6.18	6.32	6.50	6.32	6.82
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	5.243 (1.394)	4.617 (1.719)	4.473 (1.068)	4.557 (1.319)	5.037 (1.561)	4.250 (1.117)	5.133 (1.192)	4.758 (1.353)
		Min	3.00	2.64	1.82	2.68	3.18	2.50	3.21	1.82
		Median	5.250	4.160	4.750	4.340	4.930	4.680	4.960	4.680
		Max	7.32	7.85	5.68	6.82	7.50	5.82	7.60	7.85

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Urea Nitrogen [mmol/L]	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	4.330 (0.801)	4.267 (1.241)	3.825 (0.864)	3.800 (1.029)	4.345 (1.438)	3.467 (1.247)	3.503 (1.026)	3.934 (1.129)
		Min	3.18	2.89	1.68	2.07	2.50	1.32	2.32	1.32
		Median	4.320	3.910	4.000	3.930	4.180	3.070	3.305	4.000
		Max	6.50	6.68	5.18	5.78	6.82	5.32	5.60	6.82
	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	5.018 (1.109)	4.733 (1.390)	4.235 (1.126)	4.769 (1.345)	4.872 (1.538)	4.596 (1.286)	4.288 (1.059)	4.644 (1.258)
		Min	3.68	2.50	1.68	2.50	2.50	2.71	2.89	1.68
		Median	4.590	4.925	4.500	4.730	4.750	4.605	4.250	4.500
		Max	7.00	7.28	6.00	6.39	7.50	6.57	6.21	7.50
	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	4.998 (0.767)	4.130 (1.070)	4.277 (1.083)	4.543 (1.332)	5.077 (1.320)	4.304 (1.202)	4.510 (1.563)	4.555 (1.217)
		Min	3.39	2.61	1.86	3.14	2.86	2.00	2.43	1.86
		Median	4.980	4.445	4.280	4.210	5.175	4.430	4.550	4.610
		Max	5.93	6.35	5.82	7.78	6.71	5.60	8.00	8.00

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Urea Nitrogen [mmol/L]	Day 50	n	11	12	11	12	12	12	12	82
		Mean (SD)	5.115 (1.573)	4.090 (1.029)	4.865 (1.792)	4.619 (0.719)	5.027 (1.331)	4.518 (1.477)	4.531 (1.639)	4.673 (1.387)
		Min	2.46	2.53	1.71	3.39	3.28	2.28	1.79	1.71
		Median	5.360	3.945	4.710	4.570	4.925	4.430	4.445	4.660
		Max	8.57	6.14	8.32	5.89	7.57	7.14	7.07	8.57

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Alanine Aminotransferase [U/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	19.75 (8.29)	17.08 (7.42)	18.33 (6.75)	18.39 (7.38)	20.81 (9.14)
		Min	6.0	8.0	10.0	6.0	6.0
		Median	19.50	16.50	17.00	17.00	18.00
		Max	33.0	37.0	31.0	37.0	47.0
	Day 1	n	12	12	12	36	120
		Mean (SD)	18.75 (7.29)	15.75 (4.94)	18.83 (4.30)	17.78 (5.68)	19.23 (8.54)
		Min	6.0	7.0	12.0	6.0	2.5
		Median	18.50	16.50	18.00	18.00	18.00
		Max	29.0	25.0	28.0	29.0	48.0
	Day 2	n	12	12	12	36	120
		Mean (SD)	17.58 (6.67)	14.83 (3.83)	18.50 (5.66)	16.97 (5.58)	18.32 (7.93)
		Min	7.0	8.0	10.0	7.0	2.5
		Median	16.50	15.00	17.00	16.00	16.00
		Max	28.0	22.0	28.0	28.0	44.0

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Alanine Aminotransferase [U/L]	Day 8	n	12	12	12	36	120
		Mean (SD)	18.67 (7.36)	15.58 (4.40)	24.33 (17.57)	19.53 (11.56)	19.87 (10.42)
		Min	9.0	10.0	14.0	9.0	6.0
		Median	18.50	16.00	18.00	17.00	17.00
		Max	35.0	23.0	77.0	77.0	77.0
	Day 29	n	12	12	12	36	117
		Mean (SD)	17.50 (7.68)	17.92 (9.22)	26.58 (15.07)	20.67 (11.61)	22.91 (15.26)
		Min	8.0	6.0	14.0	6.0	6.0
		Median	15.50	18.00	21.00	17.00	19.00
		Max	38.0	42.0	55.0	55.0	117.0
	Day 50	n	12	0	0	12	94
		Mean (SD)	19.33 (9.41)	- (-)	- (-)	19.33 (9.41)	18.51 (8.37)
		Min	7.0	-	-	7.0	6.0
		Median	18.00	-	-	18.00	17.00
		Max	41.0	-	-	41.0	47.0

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Albumin [g/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	46.3 (1.9)	43.4 (2.1)	43.7 (1.7)	44.4 (2.3)	45.8 (2.7)
		Min	43	40	40	40	39
		Median	46.0	44.0	44.0	44.0	46.0
		Max	50	48	46	50	52
	Day 1	n	12	12	12	36	120
		Mean (SD)	43.5 (1.5)	40.8 (2.4)	43.5 (1.4)	42.6 (2.2)	44.2 (2.9)
		Min	41	37	41	37	37
		Median	44.0	41.0	43.5	43.0	44.0
		Max	47	46	46	47	50
	Day 2	n	12	12	12	36	120
		Mean (SD)	41.8 (2.1)	40.6 (2.6)	42.5 (2.6)	41.6 (2.5)	43.4 (2.8)
		Min	38	37	37	37	35
		Median	41.5	40.5	42.5	42.0	44.0
		Max	45	45	47	47	48

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Albumin [g/L]	Day 8	n	12	12	12	36	120
		Mean (SD)	43.3 (1.9)	41.1 (2.2)	42.6 (1.8)	42.3 (2.1)	43.8 (2.7)
		Min	40	38	40	38	38
		Median	43.0	41.0	42.0	42.0	44.0
		Max	46	46	46	46	50
	Day 29	n	12	12	12	36	117
		Mean (SD)	42.6 (2.2)	41.3 (3.4)	43.0 (1.8)	42.3 (2.6)	43.8 (2.7)
		Min	40	35	40	35	35
		Median	42.0	41.5	43.0	42.0	44.0
		Max	47	46	46	47	50
	Day 50	n	12	0	0	12	94
		Mean (SD)	44.3 (1.9)	- (-)	- (-)	44.3 (1.9)	44.3 (2.9)
		Min	41	-	-	41	36
		Median	44.0	-	-	44.0	44.0
		Max	48	-	-	48	51

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Alkaline Phosphatase [U/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	66.67 (20.03)	77.92 (15.39)	63.08 (12.95)	69.22 (17.16)	66.38 (17.80)
		Min	37.0	57.0	47.0	37.0	37.0
		Median	58.50	73.00	57.50	68.00	63.50
		Max	112.0	107.0	87.0	112.0	115.0
	Day 1	n	12	12	12	36	120
		Mean (SD)	65.00 (20.52)	74.75 (15.59)	62.92 (12.87)	67.56 (16.97)	63.69 (18.11)
		Min	35.0	57.0	46.0	35.0	2.5
		Median	58.50	72.50	61.00	63.50	61.50
		Max	106.0	107.0	83.0	107.0	121.0
	Day 2	n	12	12	12	36	120
		Mean (SD)	64.83 (17.91)	76.00 (17.89)	62.92 (12.30)	67.92 (16.83)	64.73 (17.43)
		Min	39.0	53.0	45.0	39.0	35.0
		Median	58.00	74.00	59.50	64.50	62.50
		Max	98.0	116.0	80.0	116.0	129.0

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Alkaline Phosphatase [U/L]	Day 8	n	12	12	12	36	120
		Mean (SD)	69.17 (20.63)	74.42 (17.38)	60.00 (9.65)	67.86 (17.16)	63.38 (16.75)
		Min	41.0	57.0	46.0	41.0	36.0
		Median	65.00	67.00	59.00	63.00	61.00
		Max	112.0	113.0	78.0	113.0	125.0
	Day 29	n	12	12	12	36	117
		Mean (SD)	66.17 (18.15)	72.08 (15.58)	57.33 (10.84)	65.19 (15.95)	63.38 (17.24)
		Min	42.0	55.0	46.0	42.0	33.0
		Median	62.50	69.00	54.50	62.50	61.00
		Max	105.0	109.0	83.0	109.0	125.0
	Day 50	n	12	0	0	12	94
		Mean (SD)	65.58 (19.55)	- (-)	- (-)	65.58 (19.55)	64.60 (17.77)
		Min	37.0	-	-	37.0	33.0
		Median	62.00	-	-	62.00	62.00
		Max	109.0	-	-	109.0	129.0

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Amylase [U/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	66.0 (26.6)	65.2 (21.8)	78.4 (25.2)	69.9 (24.7)	65.9 (20.5)
		Min	34	33	35	33	19
		Median	58.0	64.0	78.5	67.0	65.0
		Max	128	113	131	131	131
	Day 1	n	12	12	12	36	120
		Mean (SD)	67.4 (28.8)	67.5 (20.2)	79.3 (28.2)	71.4 (25.9)	65.1 (22.9)
		Min	32	37	37	32	23
		Median	63.5	63.0	78.0	66.5	62.0
		Max	139	108	139	139	144
	Day 2	n	12	12	12	36	120
		Mean (SD)	65.0 (28.0)	67.3 (21.2)	78.2 (28.5)	70.1 (26.0)	63.6 (21.3)
		Min	33	37	40	33	22
		Median	54.5	63.5	75.5	64.5	61.5
		Max	132	109	146	146	146

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Amylase [U/L]	Day 8	n	12	12	12	36	120
		Mean (SD)	65.2 (24.3)	65.4 (18.5)	80.3 (33.6)	70.3 (26.5)	65.2 (23.2)
		Min	35	32	41	32	24
		Median	57.5	67.0	73.5	64.5	62.0
		Max	121	91	145	145	145
	Day 29	n	12	12	12	36	117
		Mean (SD)	72.9 (39.9)	65.8 (19.1)	76.7 (25.8)	71.8 (29.1)	66.1 (25.6)
		Min	40	35	39	35	23
		Median	59.0	61.0	74.0	63.0	61.0
		Max	181	102	133	181	204
	Day 50	n	12	0	0	12	94
		Mean (SD)	67.8 (23.4)	- (-)	- (-)	67.8 (23.4)	62.5 (18.3)
		Min	39	-	-	39	22
		Median	67.5	-	-	67.5	62.0
		Max	114	-	-	114	114

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Aspartate Aminotransferase [U/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	21.75 (4.27)	22.00 (4.26)	20.92 (4.19)	21.56 (4.14)	21.53 (5.46)
		Min	14.0	16.0	14.0	14.0	11.0
		Median	23.50	22.50	20.00	22.00	21.00
		Max	27.0	32.0	30.0	32.0	41.0
	Day 1	n	12	12	12	36	120
		Mean (SD)	20.58 (4.03)	21.00 (3.28)	21.33 (4.14)	20.97 (3.74)	20.59 (5.98)
		Min	14.0	14.0	12.0	12.0	11.0
		Median	21.50	21.50	22.50	22.00	20.00
		Max	25.0	26.0	28.0	28.0	59.0
	Day 2	n	12	12	12	36	120
		Mean (SD)	19.25 (3.55)	21.08 (2.64)	20.67 (3.87)	20.33 (3.39)	19.14 (4.76)
		Min	13.0	16.0	12.0	12.0	2.5
		Median	20.00	21.00	21.00	21.00	19.00
		Max	25.0	26.0	25.0	26.0	38.0

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Aspartate Aminotransferase [U/L]	Day 8	n	12	12	12	36	120
		Mean (SD)	20.58 (4.78)	21.67 (2.71)	24.33 (10.64)	22.19 (6.90)	20.72 (5.58)
		Min	12.0	18.0	13.0	12.0	12.0
		Median	21.00	21.50	20.50	21.00	20.00
		Max	26.0	26.0	52.0	52.0	52.0
	Day 29	n	12	12	12	36	117
		Mean (SD)	20.92 (3.65)	20.92 (3.94)	23.92 (6.78)	21.92 (5.06)	21.35 (5.94)
		Min	13.0	16.0	18.0	13.0	12.0
		Median	21.00	20.00	21.50	20.00	20.00
		Max	26.0	30.0	40.0	40.0	44.0
	Day 50	n	12	0	0	12	94
		Mean (SD)	22.83 (6.52)	- (-)	- (-)	22.83 (6.52)	20.72 (5.04)
		Min	14.0	-	-	14.0	11.0
		Median	21.00	-	-	21.00	20.00
		Max	34.0	-	-	34.0	35.0

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Bilirubin (Serum) [µmol/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	8.97 (4.48)	8.57 (2.50)	9.75 (6.03)	9.09 (4.47)	9.25 (4.70)
		Min	4.6	3.9	5.5	3.9	1.3
		Median	7.65	9.05	6.90	8.05	8.20
		Max	18.0	12.8	25.8	25.8	33.9
	Day 1	n	12	12	12	36	120
		Mean (SD)	7.21 (2.20)	8.11 (4.49)	9.72 (5.66)	8.34 (4.36)	8.26 (4.09)
		Min	4.8	3.1	4.6	3.1	1.3
		Median	6.35	7.30	8.80	7.30	7.20
		Max	10.8	20.9	26.5	26.5	26.5
	Day 2	n	12	12	12	36	120
		Mean (SD)	9.93 (2.93)	10.07 (3.81)	10.80 (9.22)	10.26 (5.84)	9.91 (5.19)
		Min	5.5	3.4	4.3	3.4	1.3
		Median	9.75	10.25	7.45	9.65	9.00
		Max	17.1	19.2	38.0	38.0	38.0

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Bilirubin (Serum) [µmol/L]	Day 8	n	12	12	12	36	120
		Mean (SD)	7.29 (2.42)	6.91 (1.63)	9.24 (4.89)	7.81 (3.36)	7.66 (3.65)
		Min	3.6	4.1	3.9	3.6	1.3
		Median	7.00	7.35	7.80	7.35	7.10
		Max	12.3	9.1	22.1	22.1	22.1
	Day 29	n	12	12	12	36	117
		Mean (SD)	7.10 (3.43)	7.43 (1.77)	9.38 (4.49)	7.97 (3.47)	8.21 (4.40)
		Min	1.3	5.1	4.4	1.3	1.3
		Median	7.25	7.00	8.50	7.90	7.40
		Max	12.3	10.8	22.6	22.6	29.1
	Day 50	n	12	0	0	12	94
		Mean (SD)	8.31 (2.56)	- (-)	- (-)	8.31 (2.56)	8.79 (5.07)
		Min	4.4	-	-	4.4	1.3
		Median	8.20	-	-	8.20	7.95
		Max	13.7	-	-	13.7	35.9

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
C Reactive Protein [mg/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	1.117 (0.687)	1.583 (0.878)	1.592 (1.050)	1.431 (0.888)	1.042 (1.064)
		Min	0.30	0.40	0.40	0.30	0.15
		Median	0.900	1.450	1.250	1.400	0.700
		Max	2.10	3.60	3.50	3.60	6.10
	Day 1	n	12	12	12	36	120
		Mean (SD)	1.517 (2.305)	1.533 (0.822)	1.225 (1.173)	1.425 (1.528)	0.974 (1.113)
		Min	0.30	0.50	0.40	0.30	0.15
		Median	0.750	1.500	0.900	1.000	0.700
		Max	8.70	3.20	4.80	8.70	8.70
	Day 2	n	12	12	12	36	120
		Mean (SD)	3.017 (2.270)	4.167 (1.745)	5.133 (4.759)	4.106 (3.235)	3.962 (4.220)
		Min	0.60	2.30	1.30	0.60	0.15
		Median	2.350	3.550	3.900	3.350	3.000
		Max	8.00	8.00	18.80	18.80	23.70

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
C Reactive Protein [mg/L]	Day 8	n	12	12	12	36	120
		Mean (SD)	1.817 (2.187)	2.275 (1.371)	1.517 (1.085)	1.869 (1.601)	1.280 (1.197)
		Min	0.50	0.90	0.40	0.40	0.15
		Median	1.050	1.950	1.150	1.300	0.900
		Max	8.40	5.70	4.00	8.40	8.40
	Day 29	n	12	12	12	36	117
		Mean (SD)	2.000 (1.852)	1.983 (1.106)	2.175 (1.161)	2.053 (1.376)	1.659 (1.482)
		Min	0.50	0.70	0.40	0.40	0.15
		Median	1.100	1.700	2.150	1.650	1.100
		Max	6.70	4.20	4.40	6.70	7.30
	Day 50	n	12	0	0	12	94
		Mean (SD)	1.942 (3.170)	- (-)	- (-)	1.942 (3.170)	0.964 (1.334)
		Min	0.40	-	-	0.40	0.15
		Median	1.150	-	-	1.150	0.700
		Max	11.90	-	-	11.90	11.90

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Calcium [mmol/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	2.379 (0.079)	2.408 (0.060)	2.409 (0.094)	2.399 (0.078)	2.402 (0.087)
		Min	2.28	2.33	2.32	2.28	2.20
		Median	2.370	2.390	2.370	2.380	2.390
		Max	2.55	2.52	2.65	2.65	2.67
	Day 1	n	12	12	12	36	120
		Mean (SD)	2.357 (0.068)	2.342 (0.062)	2.380 (0.064)	2.359 (0.065)	2.349 (0.222)
		Min	2.25	2.27	2.23	2.23	0.10
		Median	2.360	2.315	2.380	2.370	2.370
		Max	2.45	2.45	2.46	2.46	2.58
	Day 2	n	12	12	12	36	120
		Mean (SD)	2.339 (0.072)	2.317 (0.086)	2.343 (0.100)	2.333 (0.085)	2.338 (0.080)
		Min	2.16	2.20	2.18	2.16	2.16
		Median	2.345	2.310	2.360	2.335	2.340
		Max	2.44	2.46	2.49	2.49	2.56

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Calcium [mmol/L]	Day 8	n	12	12	12	36	120
		Mean (SD)	2.375 (0.074)	2.310 (0.048)	2.343 (0.090)	2.343 (0.076)	2.348 (0.085)
		Min	2.24	2.24	2.21	2.21	2.16
		Median	2.380	2.290	2.340	2.350	2.340
		Max	2.48	2.37	2.48	2.48	2.62
	Day 29	n	12	12	12	36	117
		Mean (SD)	2.321 (0.063)	2.274 (0.051)	2.297 (0.093)	2.297 (0.072)	2.345 (0.085)
		Min	2.22	2.21	2.16	2.16	2.16
		Median	2.320	2.285	2.275	2.290	2.340
		Max	2.45	2.37	2.48	2.48	2.64
	Day 50	n	12	0	0	12	94
		Mean (SD)	2.348 (0.055)	- (-)	- (-)	2.348 (0.055)	2.367 (0.091)
		Min	2.23	-	-	2.23	2.11
		Median	2.360	-	-	2.360	2.355
		Max	2.40	-	-	2.40	2.63

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Creatinine [µmol/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	64.900 (8.784)	72.267 (14.201)	70.358 (11.163)	69.175 (11.697)	70.588 (14.653)
		Min	50.40	49.50	55.70	49.50	8.85
		Median	64.950	70.300	68.100	68.100	70.700
		Max	76.90	98.10	89.30	98.10	109.60
	Day 1	n	12	12	12	36	120
		Mean (SD)	68.725 (12.127)	65.942 (13.753)	70.725 (7.901)	68.464 (11.368)	71.959 (11.902)
		Min	48.60	46.90	58.30	46.90	46.90
		Median	68.500	63.200	68.100	67.200	70.700
		Max	84.00	92.80	83.10	92.80	111.40
	Day 2	n	12	12	12	36	120
		Mean (SD)	69.017 (12.163)	66.742 (11.702)	70.067 (10.387)	68.608 (11.199)	73.190 (13.665)
		Min	48.60	46.00	56.60	46.00	46.00
		Median	71.600	67.200	67.200	67.200	73.400
		Max	87.50	85.70	90.20	90.20	106.10

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Creatinine [µmol/L]	Day 8	n	12	12	12	36	120
		Mean (SD)	70.133 (11.010)	66.883 (12.961)	71.533 (8.397)	69.517 (10.815)	72.753 (11.940)
		Min	52.20	50.40	61.00	50.40	46.00
		Median	69.400	65.400	68.100	67.200	72.050
		Max	85.70	96.40	84.90	96.40	97.20
	Day 29	n	12	12	12	36	117
		Mean (SD)	69.250 (11.638)	66.725 (10.814)	71.383 (10.484)	69.119 (10.844)	73.391 (12.449)
		Min	53.00	48.60	59.20	48.60	47.70
		Median	69.000	68.050	69.400	69.000	73.400
		Max	84.90	82.20	92.80	92.80	102.50
	Day 50	n	12	0	0	12	94
		Mean (SD)	72.200 (13.240)	- (-)	- (-)	72.200 (13.240)	75.466 (13.430)
		Min	45.10	-	-	45.10	45.10
		Median	73.850	-	-	73.850	74.700
		Max	89.30	-	-	89.30	122.00

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Ferritin [µg/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	136.49 (173.90)	80.56 (25.33)	147.16 (101.59)	121.40 (117.59)	101.27 (96.34)
		Min	24.3	33.7	40.7	24.3	4.7
		Median	70.75	78.95	114.95	85.30	76.85
		Max	638.3	125.5	345.2	638.3	638.3
	Day 1	n	12	12	12	36	120
		Mean (SD)	135.68 (168.54)	72.01 (34.39)	144.17 (99.30)	117.28 (116.04)	96.60 (94.17)
		Min	21.9	36.9	47.7	21.9	4.9
		Median	78.25	68.55	109.50	74.90	63.85
		Max	613.2	170.0	330.9	613.2	613.2
	Day 2	n	12	12	12	36	120
		Mean (SD)	130.99 (154.64)	80.33 (35.32)	152.47 (110.41)	121.26 (112.61)	101.21 (92.87)
		Min	22.2	43.1	55.1	22.2	4.5
		Median	84.45	75.60	111.50	84.05	73.15
		Max	571.0	178.4	399.3	571.0	571.0

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Ferritin [µg/L]	Day 8	n	12	12	12	36	120
		Mean (SD)	135.92 (166.50)	82.63 (34.72)	164.06 (107.96)	127.54 (118.02)	105.44 (100.77)
		Min	23.2	45.3	50.5	23.2	5.6
		Median	78.35	68.95	130.80	85.90	66.25
		Max	619.6	173.4	377.8	619.6	619.6
	Day 29	n	12	12	12	36	117
		Mean (SD)	145.68 (176.91)	66.17 (33.51)	169.36 (121.19)	127.07 (129.65)	105.62 (107.01)
		Min	18.9	33.7	44.1	18.9	4.3
		Median	109.25	52.35	130.30	75.55	70.80
		Max	648.1	149.4	395.4	648.1	648.1
	Day 50	n	12	0	0	12	94
		Mean (SD)	118.31 (162.26)	- (-)	- (-)	118.31 (162.26)	80.04 (96.26)
		Min	13.7	-	-	13.7	4.9
		Median	76.55	-	-	76.55	51.40
		Max	599.6	-	-	599.6	599.6

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Follicle Stimulating Hormone [IU/L]	Day -30 to 0	n	2	10	7	19	35
		Mean (SD)	67.40 (-)	75.22 (23.05)	69.67 (58.35)	72.35 (37.62)	56.19 (45.32)
		Min	60.9	51.6	1.5	1.5	1.5
		Median	67.40	70.90	63.00	65.40	60.90
		Max	73.9	118.2	165.8	165.8	165.8
Gamma Glutamyl Transferase [U/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	20.3 (7.5)	15.9 (6.0)	24.5 (16.8)	20.3 (11.4)	19.9 (12.8)
		Min	12	7	9	7	5
		Median	18.5	15.5	17.5	16.5	16.0
		Max	33	29	67	67	82
	Day 1	n	12	12	12	36	120
		Mean (SD)	18.9 (5.7)	15.1 (5.6)	23.6 (16.2)	19.2 (10.7)	19.0 (12.5)
		Min	11	7	8	7	6
		Median	19.0	14.5	17.0	16.5	15.5
		Max	30	29	68	68	88

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Gamma Glutamyl Transferase [U/L]	Day 2	n	12	12	12	36	120
		Mean (SD)	17.6 (5.2)	14.9 (5.9)	23.6 (18.8)	18.7 (12.0)	18.5 (12.6)
		Min	11	6	9	6	6
		Median	17.0	15.0	16.0	16.0	15.0
		Max	30	29	78	78	83
	Day 8	n	12	12	12	36	120
		Mean (SD)	19.7 (5.7)	16.2 (6.4)	25.1 (18.6)	20.3 (12.1)	20.5 (17.3)
		Min	13	7	13	7	7
		Median	19.0	16.0	17.5	18.0	16.0
		Max	30	31	79	79	158
	Day 29	n	12	12	12	36	117
		Mean (SD)	20.2 (6.5)	17.5 (5.2)	26.9 (17.6)	21.5 (11.6)	21.8 (14.1)
		Min	12	9	11	9	5
		Median	19.0	18.0	20.0	18.0	17.0
		Max	31	28	73	73	90

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Gamma Glutamyl Transferase [U/L]	Day 50	n	12	0	0	12	94
		Mean (SD)	20.8 (6.1)	- (-)	- (-)	20.8 (6.1)	19.5 (13.1)
		Min	13	-	-	13	4
		Median	19.5	-	-	19.5	16.0
		Max	30	-	-	30	87
Glucose (Blood) [mmol/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	5.495 (0.478)	5.653 (0.304)	5.602 (0.756)	5.583 (0.534)	5.424 (0.507)
		Min	4.73	4.89	4.56	4.56	4.34
		Median	5.475	5.700	5.725	5.670	5.390
		Max	6.34	6.12	7.12	7.12	7.12
	Day 1	n	12	12	12	36	120
		Mean (SD)	5.356 (0.439)	5.508 (0.309)	5.353 (0.634)	5.406 (0.471)	5.215 (0.505)
		Min	4.67	5.06	4.78	4.67	4.00
		Median	5.395	5.445	5.035	5.365	5.170
		Max	6.12	6.00	6.51	6.51	6.62

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Glucose (Blood) [mmol/L]	Day 2	n	12	12	12	36	120
		Mean (SD)	5.328 (0.422)	5.685 (0.374)	5.596 (0.632)	5.536 (0.499)	5.286 (0.574)
		Min	4.67	5.06	4.95	4.67	3.34
		Median	5.395	5.675	5.530	5.560	5.230
		Max	5.95	6.34	6.89	6.89	7.45
	Day 8	n	12	12	12	36	120
		Mean (SD)	5.281 (0.465)	5.468 (0.460)	5.348 (0.560)	5.366 (0.489)	5.247 (0.521)
		Min	4.61	5.06	4.56	4.56	4.28
		Median	5.365	5.255	5.170	5.280	5.230
		Max	6.23	6.62	6.34	6.62	7.12
	Day 29	n	12	12	12	36	117
		Mean (SD)	5.356 (0.424)	5.504 (0.335)	5.268 (0.675)	5.376 (0.495)	5.255 (0.529)
		Min	4.67	5.12	4.67	4.67	4.17
		Median	5.340	5.480	4.920	5.255	5.170
		Max	6.00	6.00	6.73	6.73	6.89

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Glucose (Blood) [mmol/L]	Day 50	n	12	0	0	12	94
		Mean (SD)	5.415 (0.375)	- (-)	- (-)	5.415 (0.375)	5.366 (0.614)
		Min	4.78	-	-	4.78	4.23
		Median	5.475	-	-	5.475	5.340
		Max	5.89	-	-	5.89	7.28
Lipase [U/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	34.8 (12.3)	39.8 (21.0)	38.8 (13.1)	37.8 (15.6)	34.2 (13.8)
		Min	21	16	22	16	14
		Median	33.0	39.5	39.0	35.5	32.0
		Max	67	91	73	91	91
	Day 1	n	12	12	12	36	120
		Mean (SD)	34.3 (10.0)	46.5 (22.8)	39.2 (12.5)	40.0 (16.4)	36.4 (22.0)
		Min	16	18	23	16	14
		Median	35.0	47.0	38.0	38.0	31.0
		Max	53	96	74	96	218

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Lipase [U/L]	Day 2	n	12	12	12	36	120
		Mean (SD)	32.4 (9.4)	41.1 (19.1)	39.2 (14.2)	37.6 (14.9)	33.1 (13.4)
		Min	15	17	20	15	13
		Median	32.5	40.0	35.5	34.0	30.5
		Max	49	73	66	73	73
	Day 8	n	12	12	12	36	120
		Mean (SD)	37.2 (11.9)	46.1 (20.0)	43.8 (13.8)	42.3 (15.6)	36.8 (14.5)
		Min	15	16	29	15	14
		Median	38.5	47.0	43.0	42.0	34.0
		Max	57	84	80	84	85
	Day 29	n	12	12	12	36	117
		Mean (SD)	39.3 (14.5)	46.7 (23.2)	44.2 (15.5)	43.4 (17.9)	40.6 (47.5)
		Min	17	18	19	17	14
		Median	39.0	47.0	41.0	40.0	32.0
		Max	70	95	70	95	520

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Lipase [U/L]	Day 50	n	12	0	0	12	94
		Mean (SD)	37.3 (12.5)	- (-)	- (-)	37.3 (12.5)	34.0 (17.9)
		Min	17	-	-	17	11
		Median	41.5	-	-	41.5	30.5
		Max	53	-	-	53	149
Potassium [mmol/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	4.59 (0.33)	4.42 (0.27)	4.55 (0.32)	4.52 (0.31)	4.49 (0.32)
		Min	4.1	4.0	4.1	4.0	3.6
		Median	4.45	4.40	4.55	4.40	4.50
		Max	5.2	4.9	5.0	5.2	5.5
	Day 1	n	12	12	12	36	119
		Mean (SD)	4.61 (0.42)	4.38 (0.32)	4.43 (0.32)	4.47 (0.36)	4.51 (0.37)
		Min	4.1	3.9	3.9	3.9	3.7
		Median	4.75	4.40	4.40	4.40	4.50
		Max	5.3	4.9	4.9	5.3	6.7

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Potassium [mmol/L]	Day 2	n	12	12	12	36	120
		Mean (SD)	4.67 (0.33)	4.34 (0.34)	4.39 (0.26)	4.47 (0.33)	4.42 (0.37)
		Min	4.2	3.9	4.0	3.9	3.7
		Median	4.65	4.20	4.45	4.50	4.40
		Max	5.2	4.8	4.8	5.2	6.2
	Day 8	n	12	12	12	36	120
		Mean (SD)	4.65 (0.33)	4.22 (0.24)	4.43 (0.36)	4.43 (0.35)	4.43 (0.31)
		Min	4.1	3.9	3.8	3.8	3.8
		Median	4.60	4.15	4.40	4.40	4.40
		Max	5.3	4.7	5.1	5.3	5.7
	Day 29	n	12	12	12	36	117
		Mean (SD)	4.35 (0.31)	4.20 (0.20)	4.45 (0.44)	4.33 (0.34)	4.40 (0.36)
		Min	4.0	3.8	3.8	3.8	3.4
		Median	4.20	4.25	4.35	4.30	4.30
		Max	4.9	4.5	5.3	5.3	5.3

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Potassium [mmol/L]	Day 50	n	12	0	0	12	94
		Mean (SD)	4.66 (0.46)	- (-)	- (-)	4.66 (0.46)	4.54 (0.42)
		Min	4.0	-	-	4.0	3.5
		Median	4.50	-	-	4.50	4.50
		Max	5.3	-	-	5.3	5.7
Sodium [mmol/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	138.0 (2.2)	140.0 (1.3)	137.9 (2.7)	138.6 (2.3)	139.4 (2.0)
		Min	134	138	133	133	133
		Median	138.5	140.0	138.5	139.5	140.0
		Max	140	142	141	142	143
	Day 1	n	12	12	12	36	120
		Mean (SD)	141.4 (1.9)	139.5 (1.6)	138.8 (2.3)	139.9 (2.2)	139.8 (2.0)
		Min	138	136	134	134	134
		Median	141.5	139.0	139.5	140.0	140.0
		Max	144	142	141	144	144

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Sodium [mmol/L]	Day 2	n	12	12	12	36	120
		Mean (SD)	139.6 (2.7)	139.9 (1.2)	138.3 (2.2)	139.3 (2.2)	139.1 (2.1)
		Min	133	138	135	133	133
		Median	140.0	140.0	138.0	140.0	139.0
		Max	144	142	142	144	144
	Day 8	n	12	12	12	36	120
		Mean (SD)	139.1 (1.9)	140.8 (1.5)	138.8 (2.9)	139.6 (2.3)	139.7 (1.8)
		Min	136	138	131	131	131
		Median	139.0	141.0	139.0	140.0	140.0
		Max	143	143	142	143	143
	Day 29	n	12	12	12	36	117
		Mean (SD)	140.7 (2.2)	140.0 (1.1)	139.8 (2.6)	140.1 (2.1)	140.0 (1.8)
		Min	137	139	134	134	134
		Median	141.0	140.0	139.5	140.0	140.0
		Max	144	142	144	144	144

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Sodium [mmol/L]	Day 50	n	12	0	0	12	94
		Mean (SD)	139.8 (2.7)	- (-)	- (-)	139.8 (2.7)	139.9 (1.8)
		Min	134	-	-	134	134
		Median	140.5	-	-	140.5	140.0
		Max	143	-	-	143	144
Urea Nitrogen [mmol/L]	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	4.883 (1.207)	4.216 (1.527)	5.215 (0.810)	4.771 (1.255)	4.536 (1.190)
		Min	2.78	1.75	3.71	1.75	1.75
		Median	4.985	4.320	5.125	4.980	4.500
		Max	7.32	6.57	6.60	7.32	7.32
	Day 1	n	12	12	12	36	120
		Mean (SD)	4.729 (1.177)	4.630 (1.153)	5.373 (1.083)	4.911 (1.154)	4.804 (1.294)
		Min	2.03	2.68	3.50	2.03	1.82
		Median	4.870	4.735	5.410	4.925	4.800
		Max	6.18	6.93	7.28	7.28	7.85

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Urea Nitrogen [mmol/L]	Day 2	n	12	12	12	36	120
		Mean (SD)	4.099 (1.143)	3.948 (0.797)	4.510 (0.858)	4.186 (0.949)	4.009 (1.080)
		Min	2.39	2.96	3.25	2.39	1.32
		Median	3.980	3.805	4.235	4.070	4.000
		Max	6.00	5.53	6.10	6.10	6.82
	Day 8	n	12	12	12	36	120
		Mean (SD)	4.525 (1.100)	4.407 (1.237)	5.557 (1.144)	4.829 (1.244)	4.700 (1.251)
		Min	2.32	2.82	3.96	2.32	1.68
		Median	4.550	4.395	6.050	4.660	4.570
		Max	6.25	6.57	7.21	7.21	7.50
	Day 29	n	12	12	12	36	117
		Mean (SD)	4.578 (1.098)	4.201 (1.093)	5.575 (1.353)	4.785 (1.295)	4.626 (1.240)
		Min	2.14	2.39	4.14	2.14	1.86
		Median	4.730	4.180	5.050	4.860	4.640
		Max	6.25	6.03	8.82	8.82	8.82

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-1: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Urea Nitrogen [mmol/L]	Day 50	n	12	0	0	12	94
		Mean (SD)	4.847 (1.306)	- (-)	- (-)	4.847 (1.306)	4.695 (1.372)
		Min	2.28	-	-	2.28	1.71
		Median	4.805	-	-	4.805	4.660
		Max	7.14	-	-	7.14	8.57

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.3-1: Laboratory: Descriptive statistics, continuous (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
pH	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	5.96 (0.81)	5.88 (0.93)	6.00 (0.90)	6.08 (1.06)	6.04 (0.96)	5.79 (0.86)	6.17 (0.91)	5.99 (0.90)
		Min	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
		Median	6.00	5.75	6.50	6.25	6.25	5.50	6.50	6.00
		Max	7.0	7.0	7.0	8.0	7.0	7.0	7.0	8.0
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	5.83 (0.81)	6.08 (0.95)	5.38 (0.71)	6.17 (1.11)	5.67 (0.98)	5.75 (0.97)	6.00 (1.11)	5.84 (0.96)
		Min	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
		Median	6.00	6.25	5.00	6.50	5.00	5.00	5.75	5.00
		Max	7.0	8.0	7.0	8.0	8.0	7.0	8.0	8.0
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	6.42 (0.87)	6.46 (0.86)	5.83 (1.03)	6.54 (0.89)	6.13 (0.91)	6.33 (1.13)	6.29 (0.96)	6.29 (0.95)
		Min	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
		Median	6.50	6.50	5.50	7.00	6.25	6.50	6.25	6.50
		Max	8.0	8.0	8.0	8.0	7.0	8.0	8.0	8.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.3-1: Laboratory: Descriptive statistics, continuous (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
pH	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	5.96 (0.99)	6.50 (1.07)	5.58 (0.90)	6.33 (1.05)	5.83 (0.94)	5.63 (1.00)	6.00 (1.02)	5.98 (1.01)
		Min	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
		Median	6.00	6.75	5.00	6.25	6.00	5.00	6.00	6.00
		Max	8.0	8.0	7.0	8.0	8.0	8.0	8.0	8.0
	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	6.00 (0.74)	6.58 (1.22)	5.41 (0.74)	5.91 (1.14)	5.71 (0.78)	5.59 (0.74)	6.46 (0.96)	5.96 (0.98)
		Min	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
		Median	6.00	6.75	5.00	5.00	5.50	5.00	6.75	6.00
		Max	7.0	9.0	7.0	8.0	7.0	7.0	8.0	9.0
	Day 50	n	11	12	12	12	12	12	12	83
		Mean (SD)	6.00 (1.07)	5.79 (0.89)	5.58 (0.76)	5.88 (0.96)	6.04 (0.58)	5.54 (0.84)	6.50 (1.22)	5.90 (0.94)
		Min	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
		Median	6.00	5.50	5.00	6.00	6.00	5.00	6.50	6.00
		Max	8.0	7.0	7.0	8.0	7.0	7.0	9.0	9.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.3-1: Laboratory: Descriptive statistics, continuous (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Specific Gravity	Day -30 to 0	n	12	12	12	12	12	12	12	84
		Mean (SD)	1.0150 (0.0064)	1.0117 (0.0083)	1.0129 (0.0075)	1.0108 (0.0063)	1.0142 (0.0063)	1.0158 (0.0051)	1.0096 (0.0062)	1.0129 (0.0068)
		Min	1.005	1.000	1.005	1.000	1.005	1.005	1.005	1.000
		Median	1.0150	1.0100	1.0150	1.0100	1.0150	1.0150	1.0075	1.0150
		Max	1.025	1.025	1.025	1.020	1.025	1.025	1.025	1.025
	Day 1	n	12	12	12	12	12	12	12	84
		Mean (SD)	1.0163 (0.0053)	1.0125 (0.0072)	1.0154 (0.0072)	1.0125 (0.0069)	1.0175 (0.0045)	1.0158 (0.0060)	1.0121 (0.0058)	1.0146 (0.0063)
		Min	1.005	1.005	1.005	1.005	1.010	1.010	1.005	1.005
		Median	1.0150	1.0100	1.0175	1.0125	1.0200	1.0150	1.0100	1.0150
		Max	1.025	1.025	1.025	1.025	1.025	1.025	1.025	1.025
	Day 2	n	12	12	12	12	12	12	12	84
		Mean (SD)	1.0146 (0.0033)	1.0096 (0.0054)	1.0154 (0.0054)	1.0088 (0.0043)	1.0133 (0.0054)	1.0150 (0.0052)	1.0113 (0.0048)	1.0126 (0.0053)
		Min	1.010	1.000	1.005	1.005	1.005	1.010	1.005	1.000
		Median	1.0150	1.0100	1.0150	1.0075	1.0150	1.0150	1.0100	1.0100
		Max	1.020	1.020	1.025	1.015	1.020	1.025	1.020	1.025

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.3-1: Laboratory: Descriptive statistics, continuous (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Specific Gravity	Day 8	n	12	12	12	12	12	12	12	84
		Mean (SD)	1.0158 (0.0036)	1.0117 (0.0065)	1.0163 (0.0083)	1.0129 (0.0069)	1.0179 (0.0045)	1.0163 (0.0071)	1.0129 (0.0078)	1.0148 (0.0067)
		Min	1.010	1.005	1.005	1.005	1.010	1.005	1.005	1.005
		Median	1.0150	1.0100	1.0200	1.0100	1.0200	1.0200	1.0125	1.0150
		Max	1.020	1.025	1.030	1.025	1.025	1.025	1.025	1.030
	Day 29	n	12	12	11	11	12	11	12	81
		Mean (SD)	1.0167 (0.0058)	1.0125 (0.0069)	1.0150 (0.0074)	1.0141 (0.0066)	1.0171 (0.0050)	1.0177 (0.0047)	1.0133 (0.0058)	1.0152 (0.0061)
		Min	1.005	1.005	1.005	1.005	1.005	1.010	1.005	1.005
		Median	1.0150	1.0125	1.0150	1.0150	1.0175	1.0200	1.0125	1.0150
		Max	1.025	1.025	1.025	1.025	1.025	1.025	1.020	1.025
	Day 50	n	11	12	12	12	12	12	12	83
		Mean (SD)	1.0164 (0.0071)	1.0163 (0.0074)	1.0171 (0.0062)	1.0129 (0.0045)	1.0150 (0.0060)	1.0150 (0.0071)	1.0142 (0.0067)	1.0152 (0.0064)
		Min	1.005	1.005	1.005	1.005	1.005	1.000	1.005	1.000
		Median	1.0150	1.0150	1.0200	1.0125	1.0150	1.0150	1.0150	1.0150
		Max	1.025	1.030	1.025	1.020	1.025	1.025	1.025	1.030

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.3-1: Laboratory: Descriptive statistics, continuous (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
pH	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	6.21 (1.34)	5.79 (1.30)	5.92 (1.06)	5.97 (1.22)	5.98 (1.00)
		Min	5.0	5.0	5.0	5.0	5.0
		Median	5.75	5.00	5.50	5.00	6.00
		Max	8.0	9.0	8.0	9.0	9.0
	Day 1	n	12	12	12	36	120
		Mean (SD)	6.21 (1.12)	5.58 (0.76)	5.88 (0.86)	5.89 (0.93)	5.85 (0.95)
		Min	5.0	5.0	5.0	5.0	5.0
		Median	6.75	5.00	6.00	6.00	5.50
		Max	8.0	7.0	7.0	8.0	8.0
	Day 2	n	12	12	12	36	120
		Mean (SD)	6.67 (1.21)	6.88 (1.09)	6.58 (1.06)	6.71 (1.10)	6.41 (1.01)
		Min	5.0	5.0	5.0	5.0	5.0
		Median	6.75	7.00	6.50	7.00	6.50
		Max	8.0	8.0	8.0	8.0	8.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.3-1: Laboratory: Descriptive statistics, continuous (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
pH	Day 8	n	12	12	12	36	120
		Mean (SD)	6.17 (1.09)	5.88 (1.03)	6.00 (1.02)	6.01 (1.02)	5.99 (1.01)
		Min	5.0	5.0	5.0	5.0	5.0
		Median	6.50	5.50	6.00	6.00	6.00
		Max	8.0	8.0	8.0	8.0	8.0
	Day 29	n	12	12	12	36	117
		Mean (SD)	5.79 (0.99)	5.63 (0.71)	6.17 (1.03)	5.86 (0.92)	5.93 (0.96)
		Min	5.0	5.0	5.0	5.0	5.0
		Median	5.00	5.50	6.00	6.00	6.00
		Max	7.0	7.0	8.0	8.0	9.0
	Day 50	n	12	0	0	12	95
		Mean (SD)	5.83 (1.03)	- (-)	- (-)	5.83 (1.03)	5.89 (0.95)
		Min	5.0	-	-	5.0	5.0
		Median	5.00	-	-	5.00	6.00
		Max	7.0	-	-	7.0	9.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.3-1: Laboratory: Descriptive statistics, continuous (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Specific Gravity	Day -30 to 0	n	12	12	12	36	120
		Mean (SD)	1.0113 (0.0074)	1.0133 (0.0089)	1.0104 (0.0069)	1.0117 (0.0077)	1.0125 (0.0070)
		Min	1.000	1.005	1.000	1.000	1.000
		Median	1.0100	1.0125	1.0100	1.0100	1.0125
		Max	1.025	1.030	1.020	1.030	1.030
	Day 1	n	12	12	12	36	120
		Mean (SD)	1.0096 (0.0062)	1.0133 (0.0075)	1.0138 (0.0074)	1.0122 (0.0071)	1.0139 (0.0066)
		Min	1.000	1.000	1.005	1.000	1.000
		Median	1.0075	1.0150	1.0150	1.0150	1.0150
		Max	1.020	1.025	1.025	1.025	1.025
	Day 2	n	12	12	12	36	120
		Mean (SD)	1.0100 (0.0056)	1.0108 (0.0047)	1.0129 (0.0026)	1.0113 (0.0045)	1.0122 (0.0051)
		Min	1.005	1.005	1.010	1.005	1.000
		Median	1.0100	1.0100	1.0150	1.0100	1.0100
		Max	1.020	1.020	1.015	1.020	1.025

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.3-1: Laboratory: Descriptive statistics, continuous (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Specific Gravity	Day 8	n	12	12	12	36	120
		Mean (SD)	1.0096 (0.0058)	1.0108 (0.0076)	1.0133 (0.0054)	1.0113 (0.0064)	1.0138 (0.0068)
		Min	1.005	1.005	1.005	1.005	1.005
		Median	1.0075	1.0100	1.0150	1.0100	1.0150
		Max	1.020	1.030	1.020	1.030	1.030
	Day 29	n	12	12	12	36	117
		Mean (SD)	1.0138 (0.0064)	1.0121 (0.0054)	1.0138 (0.0061)	1.0132 (0.0059)	1.0146 (0.0061)
		Min	1.005	1.005	1.005	1.005	1.005
		Median	1.0125	1.0125	1.0150	1.0150	1.0150
		Max	1.025	1.020	1.025	1.025	1.025
	Day 50	n	12	0	0	12	95
		Mean (SD)	1.0142 (0.0063)	- (-)	- (-)	1.0142 (0.0063)	1.0151 (0.0064)
		Min	1.005	-	-	1.005	1.000
		Median	1.0150	-	-	1.0150	1.0150
		Max	1.025	-	-	1.025	1.030

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

Program: Tfsaf_LB_2_1.sas (Page 8 of 8)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Bacteria [/HPF]	Day -30 to 0	(+)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		+	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	0 (0)	3 (4)
		++	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (2)
		+++	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	3 (4)
		massive	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		negative	2 (17)	4 (33)	3 (25)	3 (25)	1 (8)	3 (25)	2 (17)	18 (21)
		not detectable	1 (8)	2 (17)	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	6 (7)
	Day 1	(+)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (2)
		+	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	3 (4)
		++	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		+++	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		massive	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
		negative	1 (8)	1 (8)	2 (17)	0 (0)	2 (17)	1 (8)	3 (25)	10 (12)
		not detectable	3 (25)	2 (17)	2 (17)	0 (0)	1 (8)	1 (8)	1 (8)	10 (12)
	Day 2	(+)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (2)
		+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Bacteria [/HPF]	Day 2	++	2 (17)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	6 (7)
		+++	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		massive	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		negative	3 (25)	1 (8)	1 (8)	0 (0)	1 (8)	3 (25)	2 (17)	11 (13)
		not detectable	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	2 (17)	1 (8)	6 (7)
	Day 8	(+)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (2)
		+	3 (25)	0 (0)	2 (17)	0 (0)	1 (8)	2 (17)	0 (0)	8 (10)
		++	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		+++	1 (8)	2 (17)	0 (0)	0 (0)	0 (0)	2 (17)	1 (8)	6 (7)
		massive	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		negative	1 (8)	1 (8)	2 (17)	0 (0)	0 (0)	2 (17)	0 (0)	6 (7)
		not detectable	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
	Day 29	(+)	3 (25)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (4)
		+	2 (17)	1 (8)	1 (8)	0 (0)	1 (8)	2 (17)	0 (0)	7 (8)
		++	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	2 (2)
		+++	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Bacteria [/HPF]	Day 29	negative	0 (0)	2 (17)	3 (25)	1 (8)	2 (17)	1 (8)	4 (33)	13 (15)
		not detectable	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
	Day 50	(+)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		+	0 (0)	2 (17)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	5 (6)
		++	2 (17)	0 (0)	0 (0)	2 (17)	2 (17)	1 (8)	0 (0)	7 (8)
		negative	2 (17)	2 (17)	2 (17)	1 (8)	0 (0)	4 (33)	1 (8)	12 (14)
		not detectable	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	6 (7)
Bilirubin (Urine) [µmol/L]	Day -30 to 0	negative	11 (92)	11 (92)	11 (92)	12 (100)	11 (92)	10 (83)	12 (100)	78 (93)
		17.0	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	2 (17)	0 (0)	6 (7)
	Day 1	negative	11 (92)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	80 (95)
		17.0	1 (8)	0 (0)	1 (8)	1 (8)	0 (0)	1 (8)	0 (0)	4 (5)
	Day 2	negative	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	11 (92)	82 (98)
		17.0	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
	Day 8	negative	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	9 (75)	11 (92)	79 (94)
		17.0	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	3 (25)	1 (8)	5 (6)
	Day 29	negative	12 (100)	11 (92)	11 (92)	11 (92)	12 (100)	9 (75)	11 (92)	77 (92)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Bilirubin (Urine) [µmol/L]	Day 29	17.0	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	2 (17)	1 (8)	4 (5)
	Day 50	negative	9 (75)	12 (100)	11 (92)	12 (100)	11 (92)	10 (83)	12 (100)	77 (92)
		17.0	2 (17)	0 (0)	1 (8)	0 (0)	1 (8)	2 (17)	0 (0)	6 (7)
Casts [/HPF]	Day -30 to 0	negative	4 (33)	4 (33)	6 (50)	3 (25)	2 (17)	6 (50)	2 (17)	27 (32)
		not detectable	1 (8)	2 (17)	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	6 (7)
	Day 1	negative	3 (25)	1 (8)	3 (25)	2 (17)	2 (17)	2 (17)	4 (33)	17 (20)
		positive	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
		not detectable	3 (25)	2 (17)	2 (17)	0 (0)	1 (8)	1 (8)	1 (8)	10 (12)
	Day 2	negative	5 (42)	3 (25)	1 (8)	2 (17)	2 (17)	4 (33)	4 (33)	21 (25)
		not detectable	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	2 (17)	1 (8)	6 (7)
	Day 8	negative	4 (33)	3 (25)	4 (33)	0 (0)	3 (25)	6 (50)	1 (8)	21 (25)
		not detectable	1 (8)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	5 (6)
	Day 29	negative	5 (42)	5 (42)	4 (33)	2 (17)	3 (25)	3 (25)	4 (33)	26 (31)
		not detectable	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
	Day 50	negative	4 (33)	4 (33)	3 (25)	3 (25)	2 (17)	6 (50)	2 (17)	24 (29)
		not detectable	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	6 (7)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 4 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Crystals [/HPF]	Day -30 to 0	negative	3 (25)	4 (33)	5 (42)	3 (25)	2 (17)	6 (50)	2 (17)	25 (30)
		positive	2 (17)	2 (17)	3 (25)	0 (0)	1 (8)	0 (0)	0 (0)	8 (10)
	Day 1	negative	3 (25)	1 (8)	3 (25)	1 (8)	2 (17)	3 (25)	4 (33)	17 (20)
		positive	2 (17)	2 (17)	2 (17)	1 (8)	1 (8)	1 (8)	1 (8)	10 (12)
		not detectable	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 2	negative	4 (33)	3 (25)	1 (8)	2 (17)	2 (17)	4 (33)	4 (33)	20 (24)
		positive	1 (8)	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	1 (8)	6 (7)
		not detectable	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
	Day 8	negative	4 (33)	3 (25)	4 (33)	0 (0)	3 (25)	6 (50)	1 (8)	21 (25)
		positive	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	3 (4)
		not detectable	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 29	negative	3 (25)	4 (33)	4 (33)	2 (17)	3 (25)	3 (25)	4 (33)	23 (27)
		positive	2 (17)	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	6 (7)
		not detectable	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 50	negative	4 (33)	2 (17)	3 (25)	3 (25)	2 (17)	6 (50)	2 (17)	22 (26)
		positive	1 (8)	3 (25)	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	8 (10)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 5 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Epithelial Cells [/HPF]	Day -30 to 0	negative	1 (8)	3 (25)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	6 (7)
		0-2	1 (8)	1 (8)	3 (25)	0 (0)	1 (8)	3 (25)	1 (8)	10 (12)
		3-6	1 (8)	0 (0)	1 (8)	2 (17)	1 (8)	0 (0)	1 (8)	6 (7)
		7-10	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	3 (4)
		11-20	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		not detectable	1 (8)	2 (17)	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	6 (7)
	Day 1	massive	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		negative	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		0-2	0 (0)	1 (8)	2 (17)	1 (8)	0 (0)	1 (8)	2 (17)	7 (8)
		3-6	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	2 (2)
		7-10	1 (8)	0 (0)	1 (8)	0 (0)	2 (17)	0 (0)	1 (8)	5 (6)
		11-20	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
		21-50	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
		not detectable	2 (17)	2 (17)	2 (17)	0 (0)	1 (8)	1 (8)	1 (8)	9 (11)
	Day 2	massive	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
		negative	2 (17)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	6 (7)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 6 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Epithelial Cells [/HPF]	Day 2	0-2	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (17)	4 (5)
		3-6	2 (17)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	5 (6)
		7-10	1 (8)	1 (8)	0 (0)	1 (8)	0 (0)	3 (25)	0 (0)	6 (7)
		not detectable	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	1 (8)	5 (6)
	Day 8	massive	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		negative	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	4 (33)	0 (0)	5 (6)
		0-2	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	4 (5)
		3-6	2 (17)	0 (0)	3 (25)	0 (0)	2 (17)	0 (0)	0 (0)	7 (8)
		7-10	0 (0)	1 (8)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	3 (4)
		21-50	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
		not detectable	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
	Day 29	massive	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		negative	0 (0)	3 (25)	1 (8)	1 (8)	0 (0)	1 (8)	2 (17)	8 (10)
		0-2	3 (25)	1 (8)	2 (17)	0 (0)	1 (8)	0 (0)	2 (17)	9 (11)
		3-6	1 (8)	1 (8)	1 (8)	1 (8)	2 (17)	0 (0)	0 (0)	6 (7)
		7-10	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	3 (4)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 7 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Epithelial Cells [/HPF]	Day 29	not detectable	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	3 (4)
	Day 50	negative	0 (0)	2 (17)	2 (17)	0 (0)	0 (0)	1 (8)	1 (8)	6 (7)
		0-2	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	2 (17)	0 (0)	5 (6)
		3-6	1 (8)	2 (17)	0 (0)	2 (17)	1 (8)	3 (25)	1 (8)	10 (12)
		7-10	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		11-20	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		>50	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	6 (7)
Erythrocytes (Urine) [/HPF]	Day -30 to 0	negative	0 (0)	2 (17)	2 (17)	1 (8)	0 (0)	2 (17)	0 (0)	7 (8)
		0-2	2 (17)	1 (8)	2 (17)	2 (17)	1 (8)	4 (33)	1 (8)	13 (15)
		3-6	1 (8)	1 (8)	2 (17)	0 (0)	1 (8)	0 (0)	1 (8)	6 (7)
		11-20	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	1 (8)	2 (17)	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	6 (7)
	Day 1	negative	1 (8)	0 (0)	2 (17)	1 (8)	0 (0)	0 (0)	3 (25)	7 (8)
		0-2	2 (17)	1 (8)	1 (8)	0 (0)	1 (8)	2 (17)	1 (8)	8 (10)
		3-6	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 8 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Erythrocytes (Urine) [/HPF]	Day 1	11-20	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
		21-50	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	3 (25)	2 (17)	2 (17)	0 (0)	1 (8)	1 (8)	1 (8)	10 (12)
	Day 2	negative	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	2 (17)	4 (5)
		0-2	3 (25)	3 (25)	0 (0)	1 (8)	2 (17)	3 (25)	2 (17)	14 (17)
		3-6	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		7-10	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	2 (2)
		not detectable	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	2 (17)	1 (8)	6 (7)
	Day 8	massive	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
		negative	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
		0-2	2 (17)	1 (8)	4 (33)	0 (0)	3 (25)	3 (25)	1 (8)	14 (17)
		3-6	2 (17)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (4)
		7-10	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	1 (8)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	5 (6)
	Day 29	negative	2 (17)	1 (8)	1 (8)	2 (17)	1 (8)	0 (0)	3 (25)	10 (12)
		0-2	2 (17)	3 (25)	2 (17)	0 (0)	1 (8)	0 (0)	1 (8)	9 (11)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 9 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Erythrocytes (Urine) [/HPF]	Day 29	3-6	0 (0)	1 (8)	1 (8)	0 (0)	1 (8)	3 (25)	0 (0)	6 (7)
		7-10	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
	Day 50	negative	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	4 (33)	1 (8)	7 (8)
		0-2	2 (17)	1 (8)	2 (17)	2 (17)	1 (8)	1 (8)	1 (8)	10 (12)
		3-6	2 (17)	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	0 (0)	6 (7)
		7-10	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	6 (7)
Glucose (Urine)	Day -30 to 0	negative	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 1	negative	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 2	negative	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 8	negative	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 29	negative	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	81 (96)
	Day 50	negative	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
Hemoglobin (Urine) [10^6/L]	Day -30 to 0	negative	8 (67)	8 (67)	8 (67)	10 (83)	10 (83)	8 (67)	10 (83)	62 (74)
		10	2 (17)	3 (25)	2 (17)	2 (17)	1 (8)	3 (25)	0 (0)	13 (15)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 10 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Hemoglobin (Urine) [10^6/L]	Day -30 to 0	25	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
		50	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
		150	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
		250	1 (8)	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	4 (5)
	Day 1	negative	8 (67)	10 (83)	10 (83)	10 (83)	10 (83)	8 (67)	10 (83)	66 (79)
		10	2 (17)	2 (17)	2 (17)	1 (8)	1 (8)	2 (17)	1 (8)	11 (13)
		25	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
		50	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (2)
		150	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		250	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 2	negative	10 (83)	10 (83)	11 (92)	9 (75)	9 (75)	7 (58)	9 (75)	65 (77)
		10	1 (8)	1 (8)	1 (8)	2 (17)	1 (8)	2 (17)	0 (0)	8 (10)
		25	0 (0)	1 (8)	0 (0)	1 (8)	2 (17)	3 (25)	1 (8)	8 (10)
		50	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
		150	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		250	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 11 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Hemoglobin (Urine) [10^6/L]	Day 8	negative	8 (67)	10 (83)	9 (75)	12 (100)	10 (83)	7 (58)	11 (92)	67 (80)
		10	3 (25)	0 (0)	1 (8)	0 (0)	0 (0)	3 (25)	0 (0)	7 (8)
		25	0 (0)	2 (17)	1 (8)	0 (0)	1 (8)	1 (8)	0 (0)	5 (6)
		50	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (2)
		150	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		250	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
	Day 29	negative	11 (92)	8 (67)	8 (67)	10 (83)	10 (83)	8 (67)	11 (92)	66 (79)
		10	0 (0)	2 (17)	2 (17)	1 (8)	0 (0)	1 (8)	0 (0)	6 (7)
		25	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (17)	0 (0)	4 (5)
		150	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	3 (4)
		250	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 50	negative	7 (58)	8 (67)	8 (67)	8 (67)	11 (92)	8 (67)	11 (92)	61 (73)
		10	1 (8)	3 (25)	3 (25)	1 (8)	0 (0)	1 (8)	0 (0)	9 (11)
		25	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	3 (4)
		50	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (17)	1 (8)	5 (6)
		150	1 (8)	0 (0)	1 (8)	2 (17)	0 (0)	0 (0)	0 (0)	4 (5)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Hemoglobin (Urine) [10^6/L]	Day 50	250	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ketones [mmol/L]	Day -30 to 0	negative	12 (100)	11 (92)	11 (92)	12 (100)	8 (67)	12 (100)	11 (92)	77 (92)
		0.5	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	3 (4)
		1.5	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
		5.0	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
		15.0	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
	Day 1	negative	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	11 (92)	11 (92)	81 (96)
		0.5	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
		1.5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
	Day 2	negative	12 (100)	12 (100)	11 (92)	12 (100)	11 (92)	11 (92)	8 (67)	77 (92)
		0.5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
		1.5	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	2 (17)	5 (6)
		5.0	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
	Day 8	negative	12 (100)	12 (100)	12 (100)	11 (92)	11 (92)	9 (75)	12 (100)	79 (94)
		0.5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	0 (0)	3 (4)
		1.5	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 13 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Ketones [mmol/L]	Day 8	5.0	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 29	negative	12 (100)	12 (100)	11 (92)	10 (83)	12 (100)	9 (75)	12 (100)	78 (93)
		0.5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
		1.5	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 50	negative	10 (83)	12 (100)	11 (92)	12 (100)	10 (83)	10 (83)	10 (83)	75 (89)
		0.5	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (17)	1 (8)	5 (6)
		1.5	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
		5.0	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
Leukocytes (Urine - Dipstick) [10^6/L]	Day -30 to 0	negative	9 (75)	11 (92)	7 (58)	11 (92)	11 (92)	8 (67)	12 (100)	69 (82)
		25	1 (8)	1 (8)	3 (25)	1 (8)	0 (0)	4 (33)	0 (0)	10 (12)
		100	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (2)
		500	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	3 (4)
	Day 1	negative	8 (67)	11 (92)	8 (67)	12 (100)	10 (83)	9 (75)	9 (75)	67 (80)
		25	0 (0)	1 (8)	2 (17)	0 (0)	1 (8)	1 (8)	3 (25)	8 (10)
		100	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	0 (0)	5 (6)
		500	2 (17)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	4 (5)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 14 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Leukocytes (Urine - Dipstick) [10^6/L]	Day 2	negative	8 (67)	12 (100)	10 (83)	11 (92)	11 (92)	10 (83)	8 (67)	70 (83)
		25	2 (17)	0 (0)	2 (17)	1 (8)	1 (8)	1 (8)	2 (17)	9 (11)
		100	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	4 (5)
		500	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 8	negative	9 (75)	9 (75)	8 (67)	12 (100)	11 (92)	7 (58)	11 (92)	67 (80)
		25	1 (8)	2 (17)	2 (17)	0 (0)	1 (8)	4 (33)	0 (0)	10 (12)
		100	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	3 (4)
		500	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	4 (5)
	Day 29	negative	7 (58)	10 (83)	8 (67)	10 (83)	11 (92)	9 (75)	8 (67)	63 (75)
		25	4 (33)	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	4 (33)	12 (14)
		100	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	2 (17)	0 (0)	5 (6)
		500	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 50	negative	8 (67)	10 (83)	10 (83)	12 (100)	11 (92)	9 (75)	10 (83)	70 (83)
		25	2 (17)	1 (8)	0 (0)	0 (0)	0 (0)	3 (25)	1 (8)	7 (8)
		100	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		500	0 (0)	0 (0)	2 (17)	0 (0)	1 (8)	0 (0)	1 (8)	4 (5)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 15 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Leukocytes (Urine - Microscopy) [/HPF]	Day -30 to 0	negative	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
		0-2	2 (17)	3 (25)	1 (8)	2 (17)	1 (8)	1 (8)	2 (17)	12 (14)
		3-6	0 (0)	1 (8)	3 (25)	1 (8)	1 (8)	4 (33)	0 (0)	10 (12)
		7-10	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		21-50	2 (17)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	4 (5)
		not detectable	1 (8)	2 (17)	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	6 (7)
	Day 1	negative	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		0-2	0 (0)	1 (8)	1 (8)	2 (17)	1 (8)	1 (8)	1 (8)	7 (8)
		3-6	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	3 (25)	6 (7)
		7-10	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	3 (4)
		11-20	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		21-50	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
		not detectable	3 (25)	2 (17)	1 (8)	0 (0)	1 (8)	1 (8)	1 (8)	9 (11)
	Day 2	negative	1 (8)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	3 (4)
		0-2	1 (8)	0 (0)	0 (0)	2 (17)	0 (0)	1 (8)	3 (25)	7 (8)
		3-6	1 (8)	2 (17)	1 (8)	0 (0)	0 (0)	2 (17)	1 (8)	7 (8)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 16 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Leukocytes (Urine - Microscopy) [/HPF]	Day 2	7-10	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	3 (4)
		11-20	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	2 (17)	1 (8)	6 (7)
	Day 8	massive	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
		negative	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
		0-2	1 (8)	2 (17)	0 (0)	0 (0)	2 (17)	1 (8)	0 (0)	6 (7)
		3-6	2 (17)	1 (8)	2 (17)	0 (0)	1 (8)	1 (8)	0 (0)	7 (8)
		7-10	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	0 (0)	3 (4)
		11-20	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		not detectable	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
	Day 29	negative	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		0-2	2 (17)	3 (25)	2 (17)	1 (8)	3 (25)	1 (8)	3 (25)	15 (18)
		3-6	2 (17)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	4 (5)
		7-10	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
		11-20	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
		21-50	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Leukocytes (Urine - Microscopy) [/HPF]	Day 29	not detectable	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
	Day 50	0-2	2 (17)	2 (17)	1 (8)	0 (0)	1 (8)	5 (42)	1 (8)	12 (14)
		3-6	2 (17)	2 (17)	0 (0)	3 (25)	0 (0)	0 (0)	1 (8)	8 (10)
		7-10	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	0 (0)	3 (4)
		21-50	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	6 (7)
Nitrite	Day -30 to 0	negative	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	82 (98)
		positive	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
	Day 1	negative	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	82 (98)
		positive	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
	Day 2	negative	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	82 (98)
		positive	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
	Day 8	negative	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	82 (98)
		positive	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
	Day 29	negative	12 (100)	10 (83)	11 (92)	11 (92)	12 (100)	10 (83)	12 (100)	78 (93)
		positive	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	3 (4)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 18 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Nitrite	Day 50	negative	11 (92)	10 (83)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	81 (96)
		positive	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Protein [mg/L]	Day -30 to 0	negative	12 (100)	11 (92)	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	81 (96)
		250	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	3 (4)
	Day 1	negative	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	11 (92)	11 (92)	81 (96)
		250	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (2)
		750	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
	Day 2	negative	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	11 (92)	12 (100)	82 (98)
		250	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
		5000	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
	Day 8	negative	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	10 (83)	12 (100)	81 (96)
		250	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
		5000	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
	Day 29	negative	12 (100)	10 (83)	10 (83)	10 (83)	12 (100)	9 (75)	12 (100)	75 (89)
		250	0 (0)	2 (17)	1 (8)	1 (8)	0 (0)	1 (8)	0 (0)	5 (6)
		750	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 19 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Protein [mg/L]	Day 50	negative	11 (92)	12 (100)	10 (83)	12 (100)	12 (100)	10 (83)	12 (100)	79 (94)
		250	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (17)	0 (0)	4 (5)
Round Epithelial Cells [/HPF]	Day -30 to 0	negative	3 (25)	3 (25)	4 (33)	3 (25)	2 (17)	6 (50)	1 (8)	22 (26)
		0-2	1 (8)	1 (8)	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	5 (6)
		not detectable	1 (8)	2 (17)	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	6 (7)
	Day 1	negative	3 (25)	1 (8)	3 (25)	1 (8)	2 (17)	2 (17)	4 (33)	16 (19)
		0-2	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	2 (2)
		not detectable	3 (25)	2 (17)	2 (17)	0 (0)	1 (8)	1 (8)	1 (8)	10 (12)
	Day 2	negative	5 (42)	3 (25)	1 (8)	2 (17)	2 (17)	4 (33)	4 (33)	21 (25)
		0-2	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		not detectable	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	2 (17)	1 (8)	6 (7)
	Day 8	negative	3 (25)	3 (25)	4 (33)	0 (0)	3 (25)	6 (50)	0 (0)	19 (23)
		0-2	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
		3-6	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		not detectable	1 (8)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	5 (6)
	Day 29	negative	5 (42)	4 (33)	4 (33)	2 (17)	3 (25)	3 (25)	4 (33)	25 (30)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 20 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Round Epithelial Cells [/HPF]	Day 29	0-2	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
	Day 50	negative	4 (33)	3 (25)	2 (17)	3 (25)	2 (17)	4 (33)	1 (8)	19 (23)
		0-2	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (17)	1 (8)	5 (6)
		not detectable	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	6 (7)
Urobilinogen [µmol/L]	Day -30 to 0	normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
		17	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 1	normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
		17	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 2	normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 8	68	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	82 (98)
		17	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
	Day 29	normal	12 (100)	11 (92)	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	80 (95)
		17	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 50	normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	82 (98)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 21 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Urobilinogen [µmol/L]	Day 50	17	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 22 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Bacteria [/HPF]	Day -30 to 0	(+)	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
		+	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)
		++	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
		+++	1 (8)	4 (33)	1 (8)	6 (17)	9 (8)
		massive	0 (0)	1 (8)	1 (8)	2 (6)	2 (2)
		negative	3 (25)	0 (0)	2 (17)	5 (14)	23 (19)
		not detectable	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
	Day 1	(+)	0 (0)	0 (0)	3 (25)	3 (8)	5 (4)
		+	0 (0)	1 (8)	0 (0)	1 (3)	4 (3)
		++	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
		+++	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
		massive	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		negative	2 (17)	0 (0)	2 (17)	4 (11)	14 (12)
		not detectable	0 (0)	0 (0)	0 (0)	0 (0)	10 (8)
	Day 2	(+)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		+	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 23 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Bacteria [/HPF]	Day 2	++	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
		+++	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
		massive	0 (0)	2 (17)	0 (0)	2 (6)	2 (2)
		negative	5 (42)	0 (0)	4 (33)	9 (25)	20 (17)
		not detectable	0 (0)	0 (0)	1 (8)	1 (3)	7 (6)
	Day 8	(+)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		+	0 (0)	1 (8)	1 (8)	2 (6)	10 (8)
		++	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
		+++	0 (0)	2 (17)	0 (0)	2 (6)	8 (7)
		massive	0 (0)	3 (25)	0 (0)	3 (8)	3 (3)
		negative	3 (25)	0 (0)	4 (33)	7 (19)	13 (11)
		not detectable	0 (0)	1 (8)	0 (0)	1 (3)	5 (4)
	Day 29	(+)	0 (0)	1 (8)	0 (0)	1 (3)	4 (3)
		+	1 (8)	0 (0)	2 (17)	3 (8)	10 (8)
		++	1 (8)	1 (8)	2 (17)	4 (11)	6 (5)
		+++	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 24 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Bacteria [/HPF]	Day 29	negative	2 (17)	5 (42)	2 (17)	9 (25)	22 (18)
		not detectable	1 (8)	0 (0)	0 (0)	1 (3)	5 (4)
	Day 50	(+)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
		+	1 (8)	0 (0)	0 (0)	1 (3)	6 (5)
		++	0 (0)	0 (0)	0 (0)	0 (0)	7 (6)
		negative	3 (25)	0 (0)	0 (0)	3 (8)	15 (13)
		not detectable	1 (8)	0 (0)	0 (0)	1 (3)	7 (6)
Bilirubin (Urine) [µmol/L]	Day -30 to 0	negative	11 (92)	9 (75)	12 (100)	32 (89)	110 (92)
		17.0	1 (8)	3 (25)	0 (0)	4 (11)	10 (8)
	Day 1	negative	11 (92)	12 (100)	12 (100)	35 (97)	115 (96)
		17.0	1 (8)	0 (0)	0 (0)	1 (3)	5 (4)
	Day 2	negative	11 (92)	12 (100)	12 (100)	35 (97)	117 (98)
		17.0	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
	Day 8	negative	12 (100)	11 (92)	12 (100)	35 (97)	114 (95)
		17.0	0 (0)	1 (8)	0 (0)	1 (3)	6 (5)
	Day 29	negative	11 (92)	12 (100)	12 (100)	35 (97)	112 (93)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 25 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Bilirubin (Urine) [µmol/L]	Day 29	17.0	1 (8)	0 (0)	0 (0)	1 (3)	5 (4)
	Day 50	negative	11 (92)	0 (0)	0 (0)	11 (31)	88 (73)
		17.0	1 (8)	0 (0)	0 (0)	1 (3)	7 (6)
Casts [/HPF]	Day -30 to 0	negative	4 (33)	7 (58)	5 (42)	16 (44)	43 (36)
		not detectable	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
	Day 1	negative	2 (17)	3 (25)	5 (42)	10 (28)	27 (23)
		positive	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	0 (0)	0 (0)	0 (0)	0 (0)	10 (8)
	Day 2	negative	5 (42)	2 (17)	4 (33)	11 (31)	32 (27)
		not detectable	0 (0)	2 (17)	1 (8)	3 (8)	9 (8)
	Day 8	negative	4 (33)	5 (42)	5 (42)	14 (39)	35 (29)
		not detectable	0 (0)	2 (17)	0 (0)	2 (6)	7 (6)
	Day 29	negative	4 (33)	7 (58)	6 (50)	17 (47)	43 (36)
		not detectable	1 (8)	0 (0)	0 (0)	1 (3)	5 (4)
	Day 50	negative	5 (42)	0 (0)	0 (0)	5 (14)	29 (24)
		not detectable	1 (8)	0 (0)	0 (0)	1 (3)	7 (6)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Crystals [/HPF]	Day -30 to 0	negative	3 (25)	2 (17)	5 (42)	10 (28)	35 (29)
		positive	1 (8)	5 (42)	0 (0)	6 (17)	14 (12)
	Day 1	negative	2 (17)	3 (25)	4 (33)	9 (25)	26 (22)
		positive	0 (0)	0 (0)	1 (8)	1 (3)	11 (9)
		not detectable	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 2	negative	5 (42)	2 (17)	3 (25)	10 (28)	30 (25)
		positive	0 (0)	0 (0)	2 (17)	2 (6)	8 (7)
		not detectable	0 (0)	2 (17)	0 (0)	2 (6)	3 (3)
	Day 8	negative	4 (33)	4 (33)	5 (42)	13 (36)	34 (28)
		positive	0 (0)	2 (17)	0 (0)	2 (6)	5 (4)
		not detectable	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
	Day 29	negative	4 (33)	6 (50)	6 (50)	16 (44)	39 (33)
		positive	1 (8)	1 (8)	0 (0)	2 (6)	8 (7)
		not detectable	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 50	negative	5 (42)	0 (0)	0 (0)	5 (14)	27 (23)
		positive	1 (8)	0 (0)	0 (0)	1 (3)	9 (8)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 27 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Epithelial Cells [/HPF]	Day -30 to 0	negative	2 (17)	1 (8)	0 (0)	3 (8)	9 (8)
		0-2	2 (17)	3 (25)	3 (25)	8 (22)	18 (15)
		3-6	0 (0)	3 (25)	2 (17)	5 (14)	11 (9)
		7-10	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		11-20	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		not detectable	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
	Day 1	massive	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		negative	0 (0)	1 (8)	1 (8)	2 (6)	3 (3)
		0-2	2 (17)	2 (17)	3 (25)	7 (19)	14 (12)
		3-6	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		7-10	0 (0)	0 (0)	1 (8)	1 (3)	6 (5)
		11-20	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		21-50	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	0 (0)	0 (0)	0 (0)	0 (0)	9 (8)
	Day 2	massive	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		negative	2 (17)	1 (8)	1 (8)	4 (11)	10 (8)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 28 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Epithelial Cells [/HPF]	Day 2	0-2	3 (25)	1 (8)	2 (17)	6 (17)	10 (8)
		3-6	0 (0)	0 (0)	1 (8)	1 (3)	6 (5)
		7-10	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
		not detectable	0 (0)	2 (17)	1 (8)	3 (8)	8 (7)
	Day 8	massive	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		negative	2 (17)	1 (8)	1 (8)	4 (11)	9 (8)
		0-2	2 (17)	2 (17)	3 (25)	7 (19)	11 (9)
		3-6	0 (0)	2 (17)	1 (8)	3 (8)	10 (8)
		7-10	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		21-50	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		not detectable	0 (0)	2 (17)	0 (0)	2 (6)	6 (5)
	Day 29	massive	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		negative	0 (0)	1 (8)	2 (17)	3 (8)	11 (9)
		0-2	2 (17)	6 (50)	2 (17)	10 (28)	19 (16)
		3-6	2 (17)	0 (0)	2 (17)	4 (11)	10 (8)
		7-10	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 29 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Epithelial Cells [/HPF]	Day 29	not detectable	1 (8)	0 (0)	0 (0)	1 (3)	4 (3)
	Day 50	negative	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
		0-2	5 (42)	0 (0)	0 (0)	5 (14)	10 (8)
		3-6	0 (0)	0 (0)	0 (0)	0 (0)	10 (8)
		7-10	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		11-20	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		>50	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	1 (8)	0 (0)	0 (0)	1 (3)	7 (6)
Erythrocytes (Urine) [/HPF]	Day -30 to 0	negative	2 (17)	4 (33)	1 (8)	7 (19)	14 (12)
		0-2	1 (8)	3 (25)	4 (33)	8 (22)	21 (18)
		3-6	1 (8)	0 (0)	0 (0)	1 (3)	7 (6)
		11-20	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
	Day 1	negative	1 (8)	0 (0)	1 (8)	2 (6)	9 (8)
		0-2	1 (8)	1 (8)	4 (33)	6 (17)	14 (12)
		3-6	0 (0)	2 (17)	0 (0)	2 (6)	3 (3)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 30 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Erythrocytes (Urine) [/HPF]	Day 1	11-20	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		21-50	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	0 (0)	0 (0)	0 (0)	0 (0)	10 (8)
	Day 2	negative	1 (8)	1 (8)	0 (0)	2 (6)	6 (5)
		0-2	4 (33)	0 (0)	3 (25)	7 (19)	21 (18)
		3-6	0 (0)	1 (8)	1 (8)	2 (6)	3 (3)
		7-10	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		not detectable	0 (0)	2 (17)	1 (8)	3 (8)	9 (8)
	Day 8	massive	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		negative	0 (0)	3 (25)	1 (8)	4 (11)	6 (5)
		0-2	4 (33)	2 (17)	3 (25)	9 (25)	23 (19)
		3-6	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		7-10	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		not detectable	0 (0)	2 (17)	0 (0)	2 (6)	7 (6)
	Day 29	negative	0 (0)	5 (42)	4 (33)	9 (25)	19 (16)
		0-2	3 (25)	1 (8)	2 (17)	6 (17)	15 (13)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 31 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Erythrocytes (Urine) [/HPF]	Day 29	3-6	1 (8)	1 (8)	0 (0)	2 (6)	8 (7)
		7-10	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	1 (8)	0 (0)	0 (0)	1 (3)	5 (4)
	Day 50	negative	1 (8)	0 (0)	0 (0)	1 (3)	8 (7)
		0-2	3 (25)	0 (0)	0 (0)	3 (8)	13 (11)
		3-6	1 (8)	0 (0)	0 (0)	1 (3)	7 (6)
		7-10	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	1 (8)	0 (0)	0 (0)	1 (3)	7 (6)
Glucose (Urine)	Day -30 to 0	negative	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	Day 1	negative	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	Day 2	negative	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	Day 8	negative	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	Day 29	negative	12 (100)	12 (100)	12 (100)	36 (100)	117 (98)
	Day 50	negative	12 (100)	0 (0)	0 (0)	12 (33)	95 (79)
Hemoglobin (Urine) [10^6/L]	Day -30 to 0	negative	10 (83)	9 (75)	10 (83)	29 (81)	91 (76)
		10	1 (8)	3 (25)	1 (8)	5 (14)	18 (15)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 32 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Hemoglobin (Urine) [10^6/L]	Day -30 to 0	25	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		50	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
		150	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		250	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
	Day 1	negative	11 (92)	11 (92)	10 (83)	32 (89)	98 (82)
		10	0 (0)	1 (8)	2 (17)	3 (8)	14 (12)
		25	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		50	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
		150	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		250	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 2	negative	10 (83)	11 (92)	8 (67)	29 (81)	94 (78)
		10	2 (17)	0 (0)	3 (25)	5 (14)	13 (11)
		25	0 (0)	1 (8)	1 (8)	2 (6)	10 (8)
		50	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		150	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		250	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Hemoglobin (Urine) [10^6/L]	Day 8	negative	9 (75)	11 (92)	10 (83)	30 (83)	97 (81)
		10	3 (25)	1 (8)	1 (8)	5 (14)	12 (10)
		25	0 (0)	0 (0)	1 (8)	1 (3)	6 (5)
		50	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		150	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		250	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 29	negative	9 (75)	8 (67)	10 (83)	27 (75)	93 (78)
		10	2 (17)	4 (33)	1 (8)	7 (19)	13 (11)
		25	1 (8)	0 (0)	1 (8)	2 (6)	6 (5)
		150	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		250	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 50	negative	10 (83)	0 (0)	0 (0)	10 (28)	71 (59)
		10	1 (8)	0 (0)	0 (0)	1 (3)	10 (8)
		25	1 (8)	0 (0)	0 (0)	1 (3)	4 (3)
		50	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
		150	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 34 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Hemoglobin (Urine) [10^6/L]	Day 50	250	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ketones [mmol/L]	Day -30 to 0	negative	12 (100)	11 (92)	12 (100)	35 (97)	112 (93)
		0.5	0 (0)	1 (8)	0 (0)	1 (3)	4 (3)
		1.5	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		5.0	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		15.0	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 1	negative	12 (100)	12 (100)	12 (100)	36 (100)	117 (98)
		0.5	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		1.5	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 2	negative	12 (100)	12 (100)	11 (92)	35 (97)	112 (93)
		0.5	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		1.5	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
		5.0	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 8	negative	12 (100)	12 (100)	11 (92)	35 (97)	114 (95)
		0.5	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		1.5	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Ketones [mmol/L]	Day 8	5.0	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
	Day 29	negative	12 (100)	12 (100)	11 (92)	35 (97)	113 (94)
		0.5	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
		1.5	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 50	negative	10 (83)	0 (0)	0 (0)	10 (28)	85 (71)
		0.5	2 (17)	0 (0)	0 (0)	2 (6)	7 (6)
		1.5	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		5.0	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Leukocytes (Urine - Dipstick) [10^6/L]	Day -30 to 0	negative	10 (83)	7 (58)	7 (58)	24 (67)	93 (78)
		25	2 (17)	2 (17)	3 (25)	7 (19)	17 (14)
		100	0 (0)	2 (17)	1 (8)	3 (8)	5 (4)
		500	0 (0)	1 (8)	1 (8)	2 (6)	5 (4)
	Day 1	negative	11 (92)	10 (83)	8 (67)	29 (81)	96 (80)
		25	1 (8)	2 (17)	1 (8)	4 (11)	12 (10)
		100	0 (0)	0 (0)	3 (25)	3 (8)	8 (7)
		500	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Leukocytes (Urine - Dipstick) [10^6/L]	Day 2	negative	8 (67)	9 (75)	9 (75)	26 (72)	96 (80)
		25	1 (8)	2 (17)	3 (25)	6 (17)	15 (13)
		100	0 (0)	1 (8)	0 (0)	1 (3)	5 (4)
		500	3 (25)	0 (0)	0 (0)	3 (8)	4 (3)
	Day 8	negative	10 (83)	6 (50)	7 (58)	23 (64)	90 (75)
		25	1 (8)	2 (17)	1 (8)	4 (11)	14 (12)
		100	1 (8)	1 (8)	4 (33)	6 (17)	9 (8)
		500	0 (0)	3 (25)	0 (0)	3 (8)	7 (6)
	Day 29	negative	9 (75)	7 (58)	6 (50)	22 (61)	85 (71)
		25	1 (8)	3 (25)	4 (33)	8 (22)	20 (17)
		100	0 (0)	1 (8)	0 (0)	1 (3)	6 (5)
		500	2 (17)	1 (8)	2 (17)	5 (14)	6 (5)
	Day 50	negative	9 (75)	0 (0)	0 (0)	9 (25)	79 (66)
		25	2 (17)	0 (0)	0 (0)	2 (6)	9 (8)
		100	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
		500	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 37 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Leukocytes (Urine - Microscopy) [/HPF]	Day -30 to 0	negative	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
		0-2	3 (25)	4 (33)	2 (17)	9 (25)	21 (18)
		3-6	1 (8)	1 (8)	1 (8)	3 (8)	13 (11)
		7-10	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
		21-50	0 (0)	0 (0)	2 (17)	2 (6)	6 (5)
		not detectable	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
	Day 1	negative	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		0-2	2 (17)	1 (8)	2 (17)	5 (14)	12 (10)
		3-6	0 (0)	2 (17)	2 (17)	4 (11)	10 (8)
		7-10	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)
		11-20	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		21-50	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	0 (0)	0 (0)	0 (0)	0 (0)	9 (8)
	Day 2	negative	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		0-2	2 (17)	2 (17)	4 (33)	8 (22)	15 (13)
		3-6	1 (8)	0 (0)	0 (0)	1 (3)	8 (7)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Leukocytes (Urine - Microscopy) [/HPF]	Day 2	7-10	2 (17)	0 (0)	0 (0)	2 (6)	5 (4)
		11-20	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	0 (0)	2 (17)	1 (8)	3 (8)	9 (8)
	Day 8	massive	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		negative	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
		0-2	1 (8)	3 (25)	0 (0)	4 (11)	10 (8)
		3-6	2 (17)	0 (0)	4 (33)	6 (17)	13 (11)
		7-10	0 (0)	2 (17)	1 (8)	3 (8)	6 (5)
		11-20	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		not detectable	0 (0)	2 (17)	0 (0)	2 (6)	6 (5)
	Day 29	negative	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
		0-2	0 (0)	3 (25)	2 (17)	5 (14)	20 (17)
		3-6	2 (17)	2 (17)	2 (17)	6 (17)	10 (8)
		7-10	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
		11-20	0 (0)	1 (8)	1 (8)	2 (6)	6 (5)
		21-50	1 (8)	0 (0)	1 (8)	2 (6)	3 (3)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Leukocytes (Urine - Microscopy) [/HPF]	Day 29	not detectable	1 (8)	0 (0)	0 (0)	1 (3)	5 (4)
	Day 50	0-2	2 (17)	0 (0)	0 (0)	2 (6)	14 (12)
		3-6	3 (25)	0 (0)	0 (0)	3 (8)	11 (9)
		7-10	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		21-50	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	1 (8)	0 (0)	0 (0)	1 (3)	7 (6)
Nitrite	Day -30 to 0	negative	12 (100)	8 (67)	12 (100)	32 (89)	114 (95)
		positive	0 (0)	4 (33)	0 (0)	4 (11)	6 (5)
	Day 1	negative	12 (100)	12 (100)	12 (100)	36 (100)	118 (98)
		positive	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 2	negative	12 (100)	11 (92)	12 (100)	35 (97)	117 (98)
		positive	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
	Day 8	negative	12 (100)	10 (83)	12 (100)	34 (94)	116 (97)
		positive	0 (0)	2 (17)	0 (0)	2 (6)	4 (3)
	Day 29	negative	12 (100)	12 (100)	12 (100)	36 (100)	114 (95)
		positive	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 40 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Nitrite	Day 50	negative	12 (100)	0 (0)	0 (0)	12 (33)	93 (78)
		positive	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Protein [mg/L]	Day -30 to 0	negative	12 (100)	10 (83)	12 (100)	34 (94)	115 (96)
		250	0 (0)	2 (17)	0 (0)	2 (6)	5 (4)
	Day 1	negative	12 (100)	12 (100)	12 (100)	36 (100)	117 (98)
		250	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		750	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 2	negative	12 (100)	12 (100)	12 (100)	36 (100)	118 (98)
		250	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		5000	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 8	negative	12 (100)	12 (100)	12 (100)	36 (100)	117 (98)
		250	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		5000	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 29	negative	12 (100)	12 (100)	12 (100)	36 (100)	111 (93)
		250	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
		750	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 41 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Protein [mg/L]	Day 50	negative	11 (92)	0 (0)	0 (0)	11 (31)	90 (75)
		250	1 (8)	0 (0)	0 (0)	1 (3)	5 (4)
Round Epithelial Cells [/HPF]	Day -30 to 0	negative	4 (33)	4 (33)	3 (25)	11 (31)	33 (28)
		0-2	0 (0)	3 (25)	2 (17)	5 (14)	10 (8)
		not detectable	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
	Day 1	negative	2 (17)	3 (25)	3 (25)	8 (22)	24 (20)
		0-2	0 (0)	0 (0)	2 (17)	2 (6)	4 (3)
		not detectable	0 (0)	0 (0)	0 (0)	0 (0)	10 (8)
	Day 2	negative	4 (33)	2 (17)	3 (25)	9 (25)	30 (25)
		0-2	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
		not detectable	0 (0)	2 (17)	1 (8)	3 (8)	9 (8)
	Day 8	negative	3 (25)	3 (25)	2 (17)	8 (22)	27 (23)
		0-2	1 (8)	1 (8)	3 (25)	5 (14)	7 (6)
		3-6	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
		not detectable	0 (0)	2 (17)	0 (0)	2 (6)	7 (6)
	Day 29	negative	2 (17)	5 (42)	4 (33)	11 (31)	36 (30)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 42 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Round Epithelial Cells [/HPF]	Day 29	0-2	2 (17)	2 (17)	2 (17)	6 (17)	7 (6)
		not detectable	1 (8)	0 (0)	0 (0)	1 (3)	5 (4)
	Day 50	negative	2 (17)	0 (0)	0 (0)	2 (6)	21 (18)
		0-2	3 (25)	0 (0)	0 (0)	3 (8)	8 (7)
		not detectable	1 (8)	0 (0)	0 (0)	1 (3)	7 (6)
Urobilinogen [µmol/L]	Day -30 to 0	normal	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)
		17	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 1	normal	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)
		17	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 2	normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	Day 8	68	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		normal	12 (100)	12 (100)	12 (100)	36 (100)	118 (98)
		17	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 29	normal	12 (100)	12 (100)	12 (100)	36 (100)	116 (97)
		17	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 50	normal	12 (100)	0 (0)	0 (0)	12 (33)	94 (78)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 43 of 44)

Table 14.3.2-2.1.4-1: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Urobilinogen [µmol/L]	Day 50	17	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 44 of 44)

14.3.2-2.5 Abnormal and clinically significant values per visit

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Basophils (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	2 (17)	1 (8)	3 (25)	4 (33)	0 (0)	2 (17)	0 (0)	12 (14)
		Normal	10 (83)	11 (92)	9 (75)	8 (67)	12 (100)	10 (83)	12 (100)	72 (86)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	4 (33)	2 (17)	0 (0)	2 (17)	0 (0)	9 (11)
		Normal	11 (92)	12 (100)	8 (67)	10 (83)	12 (100)	10 (83)	12 (100)	75 (89)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 2	Abnormal (not CS)	2 (17)	0 (0)	3 (25)	0 (0)	0 (0)	1 (8)	0 (0)	6 (7)
		Normal	10 (83)	12 (100)	9 (75)	12 (100)	12 (100)	11 (92)	12 (100)	78 (93)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	3 (4)
		Normal	11 (92)	12 (100)	11 (92)	11 (92)	12 (100)	12 (100)	12 (100)	81 (96)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	3 (4)
		Normal	11 (92)	12 (100)	9 (75)	11 (92)	12 (100)	9 (75)	12 (100)	76 (90)
	Day 50	Abnormal (not CS)	1 (8)	1 (8)	4 (33)	2 (17)	0 (0)	0 (0)	1 (8)	9 (11)
		Normal	10 (83)	11 (92)	7 (58)	10 (83)	12 (100)	12 (100)	11 (92)	73 (87)
Basophils (Blood Smear) [10^9/L]	Day 1	Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 29	Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 1 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Basophils/Leukocytes (Blood) [%]	Day -30 to 0	Abnormal (not CS)	2 (17)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	3 (4)
		Normal	10 (83)	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	81 (96)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	3 (4)
		Normal	11 (92)	12 (100)	11 (92)	11 (92)	12 (100)	12 (100)	12 (100)	81 (96)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	3 (4)
		Normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	11 (92)	81 (96)
	Day 8	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	10 (83)	11 (92)	12 (100)	9 (75)	12 (100)	78 (93)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	11 (92)	12 (100)	10 (83)	11 (92)	12 (100)	12 (100)	12 (100)	80 (95)
Basophils/Leukocytes (Blood Smear) [%]	Day 1	Normal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
		Normal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 2 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Eosinophils (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 1	Abnormal (not CS)	0 (0)	2 (17)	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	4 (5)
		Normal	12 (100)	10 (83)	11 (92)	11 (92)	12 (100)	12 (100)	12 (100)	80 (95)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	0 (0)	1 (8)	2 (17)	5 (42)	10 (12)
		Normal	12 (100)	12 (100)	10 (83)	12 (100)	11 (92)	10 (83)	7 (58)	74 (88)
	Day 8	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	2 (17)	1 (8)	0 (0)	4 (5)
		Normal	11 (92)	12 (100)	11 (92)	11 (92)	10 (83)	8 (67)	12 (100)	75 (89)
	Day 50	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (8)	2 (17)	0 (0)	0 (0)	4 (5)
		Normal	11 (92)	11 (92)	11 (92)	11 (92)	10 (83)	12 (100)	12 (100)	78 (93)
Eosinophils (Blood Smear) [10^9/L]	Day 1	Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 29	Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 3 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Eosinophils/Leukocytes (Blood) [%]	Day -30 to 0	Abnormal (not CS)	1 (8)	2 (17)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	4 (5)
		Normal	11 (92)	10 (83)	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	80 (95)
	Day 1	Abnormal (not CS)	1 (8)	2 (17)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	5 (6)
		Normal	11 (92)	10 (83)	11 (92)	12 (100)	12 (100)	12 (100)	11 (92)	79 (94)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	0 (0)	2 (17)	2 (17)	5 (42)	11 (13)
		Normal	11 (92)	12 (100)	11 (92)	12 (100)	10 (83)	10 (83)	7 (58)	73 (87)
	Day 8	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	0 (0)	5 (6)
		Normal	11 (92)	11 (92)	11 (92)	12 (100)	11 (92)	11 (92)	12 (100)	79 (94)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	2 (17)	1 (8)	0 (0)	4 (5)
		Normal	11 (92)	12 (100)	11 (92)	11 (92)	10 (83)	8 (67)	12 (100)	75 (89)
	Day 50	Abnormal (not CS)	2 (17)	0 (0)	0 (0)	2 (17)	2 (17)	1 (8)	0 (0)	7 (8)
		Normal	9 (75)	12 (100)	11 (92)	10 (83)	10 (83)	11 (92)	12 (100)	75 (89)
Eosinophils/Leukocytes (Blood Smear) [%]	Day 1	Normal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 29	Normal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 4 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Erythrocytes (Blood) [10^{12}/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	1 (8)	0 (0)	2 (17)	0 (0)	5 (6)
		Normal	11 (92)	12 (100)	11 (92)	11 (92)	12 (100)	10 (83)	12 (100)	79 (94)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	3 (25)	2 (17)	1 (8)	0 (0)	0 (0)	7 (8)
		Normal	11 (92)	12 (100)	9 (75)	10 (83)	11 (92)	12 (100)	12 (100)	77 (92)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 2	Abnormal (not CS)	2 (17)	1 (8)	4 (33)	0 (0)	0 (0)	3 (25)	3 (25)	13 (15)
		Normal	10 (83)	11 (92)	8 (67)	12 (100)	12 (100)	9 (75)	9 (75)	71 (85)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	5 (42)	1 (8)	1 (8)	3 (25)	2 (17)	13 (15)
		Normal	11 (92)	12 (100)	7 (58)	11 (92)	11 (92)	9 (75)	10 (83)	71 (85)
	Day 29	Abnormal (not CS)	1 (8)	1 (8)	2 (17)	3 (25)	0 (0)	3 (25)	1 (8)	11 (13)
		Normal	11 (92)	11 (92)	9 (75)	8 (67)	12 (100)	8 (67)	11 (92)	70 (83)
	Day 50	Abnormal (not CS)	2 (17)	1 (8)	1 (8)	2 (17)	1 (8)	2 (17)	1 (8)	10 (12)
		Normal	9 (75)	11 (92)	10 (83)	10 (83)	11 (92)	10 (83)	11 (92)	72 (86)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Hematocrit [L/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 5 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Hematocrit [L/L]	Day -30 to 0	Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	82 (98)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 2	Abnormal (not CS)	1 (8)	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	6 (7)
		Normal	11 (92)	10 (83)	12 (100)	12 (100)	12 (100)	11 (92)	10 (83)	78 (93)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	3 (25)	0 (0)	0 (0)	1 (8)	3 (25)	7 (8)
		Normal	12 (100)	12 (100)	9 (75)	12 (100)	12 (100)	11 (92)	9 (75)	77 (92)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	0 (0)	1 (8)	1 (8)	1 (8)	5 (6)
		Normal	12 (100)	12 (100)	9 (75)	11 (92)	11 (92)	10 (83)	11 (92)	76 (90)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	0 (0)	4 (5)
		Normal	10 (83)	12 (100)	11 (92)	11 (92)	11 (92)	11 (92)	12 (100)	78 (93)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Hemoglobin (Blood) [mmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 6 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Hemoglobin (Blood) [mmol/L]	Day 1	Abnormal (not CS)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	10 (83)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	82 (98)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 2	Abnormal (not CS)	1 (8)	3 (25)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	7 (8)
		Normal	11 (92)	9 (75)	12 (100)	11 (92)	12 (100)	11 (92)	11 (92)	77 (92)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	3 (25)	0 (0)	2 (17)	2 (17)	3 (25)	11 (13)
		Normal	11 (92)	12 (100)	9 (75)	12 (100)	10 (83)	10 (83)	9 (75)	73 (87)
	Day 29	Abnormal (not CS)	1 (8)	1 (8)	2 (17)	1 (8)	1 (8)	1 (8)	1 (8)	8 (10)
		Normal	11 (92)	11 (92)	9 (75)	10 (83)	11 (92)	10 (83)	11 (92)	73 (87)
	Day 50	Abnormal (not CS)	2 (17)	1 (8)	2 (17)	1 (8)	1 (8)	1 (8)	0 (0)	8 (10)
		Normal	9 (75)	11 (92)	9 (75)	11 (92)	11 (92)	11 (92)	12 (100)	74 (88)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Leukocytes (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	82 (98)
	Day 1	Abnormal (not CS)	2 (17)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	5 (6)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 7 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Leukocytes (Blood) [10^9/L]	Day 1	Normal	10 (83)	11 (92)	11 (92)	12 (100)	12 (100)	11 (92)	12 (100)	79 (94)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 2	Abnormal (not CS)	0 (0)	2 (17)	2 (17)	0 (0)	1 (8)	0 (0)	1 (8)	6 (7)
		Normal	12 (100)	10 (83)	10 (83)	12 (100)	11 (92)	12 (100)	11 (92)	78 (93)
	Day 8	Abnormal (not CS)	2 (17)	1 (8)	1 (8)	0 (0)	2 (17)	2 (17)	2 (17)	10 (12)
		Normal	10 (83)	11 (92)	11 (92)	12 (100)	10 (83)	10 (83)	10 (83)	74 (88)
	Day 29	Abnormal (not CS)	2 (17)	1 (8)	1 (8)	0 (0)	2 (17)	1 (8)	1 (8)	8 (10)
		Normal	10 (83)	11 (92)	10 (83)	11 (92)	10 (83)	10 (83)	11 (92)	73 (87)
	Day 50	Abnormal (not CS)	1 (8)	2 (17)	0 (0)	1 (8)	2 (17)	0 (0)	1 (8)	7 (8)
		Normal	10 (83)	10 (83)	11 (92)	11 (92)	10 (83)	12 (100)	11 (92)	75 (89)
Lymphocytes (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	2 (17)	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	0 (0)	6 (7)
		Normal	10 (83)	11 (92)	11 (92)	11 (92)	11 (92)	12 (100)	12 (100)	78 (93)
	Day 1	Abnormal (not CS)	2 (17)	1 (8)	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	5 (6)
		Normal	10 (83)	11 (92)	11 (92)	11 (92)	12 (100)	12 (100)	12 (100)	79 (94)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 8 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Lymphocytes (Blood) [10^9/L]	Day 2	Abnormal (not CS)	2 (17)	2 (17)	6 (50)	10 (83)	10 (83)	11 (92)	10 (83)	51 (61)
		Normal	10 (83)	10 (83)	6 (50)	2 (17)	2 (17)	1 (8)	2 (17)	33 (39)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	4 (5)
		Normal	11 (92)	12 (100)	11 (92)	11 (92)	12 (100)	12 (100)	11 (92)	80 (95)
	Day 29	CS abnormal	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Abnormal (not CS)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	3 (4)
		Normal	11 (92)	11 (92)	10 (83)	11 (92)	12 (100)	9 (75)	11 (92)	75 (89)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	3 (4)
		Normal	11 (92)	12 (100)	10 (83)	11 (92)	12 (100)	12 (100)	11 (92)	79 (94)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Lymphocytes (Blood Smear) [10^9/L]	Day 1	Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 29	Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
Lymphocytes/Leukocytes (Blood) [%]	Day -30 to 0	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	3 (4)
		Normal	11 (92)	11 (92)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	81 (96)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 9 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Lymphocytes/Leukocytes (Blood) [%]	Day 1	Normal	12 (100)	12 (100)	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	82 (98)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 2	Abnormal (not CS)	0 (0)	1 (8)	3 (25)	8 (67)	6 (50)	12 (100)	10 (83)	40 (48)
		Normal	12 (100)	11 (92)	9 (75)	4 (33)	6 (50)	0 (0)	2 (17)	44 (52)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	2 (17)	2 (17)	1 (8)	1 (8)	7 (8)
		Normal	12 (100)	12 (100)	11 (92)	10 (83)	10 (83)	11 (92)	11 (92)	77 (92)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	3 (25)	0 (0)	3 (25)	0 (0)	1 (8)	7 (8)
		Normal	12 (100)	12 (100)	8 (67)	11 (92)	9 (75)	9 (75)	11 (92)	72 (86)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	11 (92)	12 (100)	10 (83)	12 (100)	12 (100)	12 (100)	12 (100)	81 (96)
Lymphocytes/Leukocytes (Blood Smear) [%]	Day 1	Normal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
		Normal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Monocytes (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 10 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Monocytes (Blood) [10^9/L]	Day 1	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 2	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	4 (33)	2 (17)	1 (8)	1 (8)	10 (12)
		Normal	11 (92)	11 (92)	12 (100)	8 (67)	10 (83)	11 (92)	11 (92)	74 (88)
	Day 8	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	3 (4)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	11 (92)	11 (92)	81 (96)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	9 (75)	12 (100)	79 (94)
	Day 50	Normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	82 (98)
Monocytes (Blood Smear) [10^9/L]	Day 1	Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 29	Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
Monocytes/Leukocytes (Blood) [%]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	11 (92)	82 (98)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	82 (98)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 11 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Monocytes/Leukocytes (Blood) [%]	Day 1	Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 2	Abnormal (not CS)	4 (33)	2 (17)	4 (33)	8 (67)	5 (42)	4 (33)	5 (42)	32 (38)
		Normal	8 (67)	10 (83)	8 (67)	4 (33)	7 (58)	8 (67)	7 (58)	52 (62)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	82 (98)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
		Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	9 (75)	11 (92)	78 (93)
	Day 50	Abnormal (not CS)	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (17)	6 (7)
		Normal	9 (75)	12 (100)	11 (92)	12 (100)	11 (92)	11 (92)	10 (83)	76 (90)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Monocytes/Leukocytes (Blood Smear) [%]	Day 1	Normal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
Neutrophils (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	83 (99)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 12 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Neutrophils (Blood) [10^9/L]	Day 1	Abnormal (not CS)	2 (17)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	0 (0)	5 (6)
		Normal	10 (83)	12 (100)	11 (92)	12 (100)	11 (92)	11 (92)	12 (100)	79 (94)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	0 (0)	3 (4)
		Normal	12 (100)	12 (100)	11 (92)	12 (100)	11 (92)	11 (92)	12 (100)	81 (96)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (8)	2 (17)	1 (8)	1 (8)	6 (7)
		Normal	12 (100)	12 (100)	11 (92)	11 (92)	10 (83)	11 (92)	11 (92)	78 (93)
	Day 29	Abnormal (not CS)	2 (17)	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	6 (7)
		Normal	10 (83)	12 (100)	10 (83)	10 (83)	11 (92)	8 (67)	12 (100)	73 (87)
	Day 50	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	4 (5)
		Normal	10 (83)	11 (92)	11 (92)	12 (100)	11 (92)	11 (92)	12 (100)	78 (93)
Neutrophils (Blood Smear) [10^9/L]	Day 1	Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 29	Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
Neutrophils/Leukocytes (Blood) [%]	Day -30 to 0	Abnormal (not CS)	1 (8)	2 (17)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	4 (5)
		Normal	11 (92)	10 (83)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	80 (95)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 13 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Neutrophils/Leukocytes (Blood) [%]	Day 1	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (2)
		Normal	12 (100)	12 (100)	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	82 (98)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	3 (25)	1 (8)	7 (58)	4 (33)	16 (19)
		Normal	12 (100)	12 (100)	11 (92)	9 (75)	11 (92)	5 (42)	8 (67)	68 (81)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	1 (8)	1 (8)	0 (0)	0 (0)	4 (5)
		Normal	12 (100)	12 (100)	10 (83)	11 (92)	11 (92)	12 (100)	12 (100)	80 (95)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	1 (8)	3 (25)	0 (0)	0 (0)	6 (7)
		Normal	12 (100)	12 (100)	9 (75)	10 (83)	9 (75)	9 (75)	12 (100)	73 (87)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
		Normal	11 (92)	12 (100)	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	81 (96)
Neutrophils/Leukocytes (Blood Smear) [%]	Day 1	Normal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
		Normal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Platelets [10^9/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	2 (2)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 14 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Platelets [10^9/L]	Day -30 to 0	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	10 (83)	82 (98)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	3 (4)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	9 (75)	81 (96)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (17)	4 (5)
		Normal	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	11 (92)	10 (83)	80 (95)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	3 (4)
		Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	12 (100)	11 (92)	81 (96)
	Day 29	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	5 (6)
		Normal	11 (92)	11 (92)	11 (92)	11 (92)	12 (100)	10 (83)	10 (83)	76 (90)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	3 (4)
		Normal	11 (92)	12 (100)	11 (92)	11 (92)	12 (100)	12 (100)	10 (83)	79 (94)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 15 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Basophils (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (6)	14 (12)
		Normal	12 (100)	11 (92)	11 (92)	34 (94)	106 (88)
	Day 1	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	2 (6)	11 (9)
		Normal	11 (92)	8 (67)	12 (100)	31 (86)	106 (88)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	114 (95)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	117 (98)
	Day 29	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	4 (3)
		Normal	12 (100)	10 (83)	12 (100)	34 (94)	110 (92)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	10 (8)
		Normal	11 (92)	0 (0)	0 (0)	11 (31)	84 (70)
Basophils (Blood Smear) [10^9/L]	Day 1	Missing	0 (0)	2 (17)	0 (0)	2 (6)	2 (2)
	Day 29	Missing	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 16 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Basophils/Leukocytes (Blood) [%]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	116 (97)
	Day 1	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (6)	5 (4)
		Normal	11 (92)	9 (75)	11 (92)	31 (86)	112 (93)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	117 (98)
	Day 8	Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		Normal	12 (100)	11 (92)	11 (92)	34 (94)	112 (93)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	12 (100)	0 (0)	0 (0)	12 (33)	92 (77)
Basophils/Leukocytes (Blood Smear) [%]	Day 1	Normal	0 (0)	2 (17)	0 (0)	2 (6)	2 (2)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 17 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Eosinophils (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	5 (4)
		Normal	11 (92)	10 (83)	11 (92)	32 (89)	112 (93)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	11 (9)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	109 (91)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	118 (98)
	Day 29	Abnormal (not CS)	1 (8)	2 (17)	1 (8)	4 (11)	8 (7)
		Normal	11 (92)	9 (75)	11 (92)	31 (86)	106 (88)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
		Normal	12 (100)	0 (0)	0 (0)	12 (33)	90 (75)
Eosinophils (Blood Smear) [10^9/L]	Day 1	Missing	0 (0)	2 (17)	0 (0)	2 (6)	2 (2)
	Day 29	Missing	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 18 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Eosinophils/Leukocytes (Blood) [%]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	116 (97)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	2 (6)	7 (6)
		Normal	11 (92)	10 (83)	10 (83)	31 (86)	110 (92)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	11 (9)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	109 (91)
	Day 8	Abnormal (not CS)	0 (0)	2 (17)	2 (17)	4 (11)	9 (8)
		Normal	12 (100)	10 (83)	10 (83)	32 (89)	111 (93)
	Day 29	Abnormal (not CS)	1 (8)	2 (17)	2 (17)	5 (14)	9 (8)
		Normal	11 (92)	9 (75)	10 (83)	30 (83)	105 (88)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	7 (6)
		Normal	12 (100)	0 (0)	0 (0)	12 (33)	87 (73)
Eosinophils/Leukocytes (Blood Smear) [%]	Day 1	Normal	0 (0)	2 (17)	0 (0)	2 (6)	2 (2)
	Day 29	Normal	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 19 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Erythrocytes (Blood) [10^{12}/L]	Day -30 to 0	Abnormal (not CS)	2 (17)	2 (17)	0 (0)	4 (11)	9 (8)
		Normal	10 (83)	10 (83)	12 (100)	32 (89)	111 (93)
	Day 1	Abnormal (not CS)	1 (8)	4 (33)	0 (0)	5 (14)	12 (10)
		Normal	10 (83)	8 (67)	12 (100)	30 (83)	107 (89)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Day 2	Abnormal (not CS)	2 (17)	2 (17)	2 (17)	6 (17)	19 (16)
		Normal	10 (83)	10 (83)	10 (83)	30 (83)	101 (84)
	Day 8	Abnormal (not CS)	4 (33)	4 (33)	0 (0)	8 (22)	21 (18)
		Normal	8 (67)	8 (67)	12 (100)	28 (78)	99 (83)
	Day 29	Abnormal (not CS)	4 (33)	3 (25)	1 (8)	8 (22)	19 (16)
		Normal	8 (67)	9 (75)	11 (92)	28 (78)	98 (82)
	Day 50	Abnormal (not CS)	3 (25)	0 (0)	0 (0)	3 (8)	13 (11)
		Normal	8 (67)	0 (0)	0 (0)	8 (22)	80 (67)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Hematocrit [L/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	3 (25)	0 (0)	4 (11)	6 (5)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 20 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Hematocrit [L/L]	Day -30 to 0	Normal	11 (92)	9 (75)	12 (100)	32 (89)	114 (95)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
		Normal	10 (83)	12 (100)	12 (100)	34 (94)	117 (98)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Day 2	Abnormal (not CS)	2 (17)	0 (0)	0 (0)	2 (6)	8 (7)
		Normal	10 (83)	12 (100)	12 (100)	34 (94)	112 (93)
	Day 8	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (6)	9 (8)
		Normal	11 (92)	11 (92)	12 (100)	34 (94)	111 (93)
	Day 29	Abnormal (not CS)	2 (17)	1 (8)	1 (8)	4 (11)	9 (8)
		Normal	10 (83)	11 (92)	11 (92)	32 (89)	108 (90)
	Day 50	Abnormal (not CS)	2 (17)	0 (0)	0 (0)	2 (6)	6 (5)
		Normal	9 (75)	0 (0)	0 (0)	9 (25)	87 (73)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Hemoglobin (Blood) [mmol/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (6)	2 (2)
		Normal	11 (92)	11 (92)	12 (100)	34 (94)	118 (98)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 21 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Hemoglobin (Blood) [mmol/L]	Day 1	Abnormal (not CS)	2 (17)	1 (8)	0 (0)	3 (8)	5 (4)
		Normal	9 (75)	11 (92)	12 (100)	32 (89)	114 (95)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Day 2	Abnormal (not CS)	2 (17)	1 (8)	1 (8)	4 (11)	11 (9)
		Normal	10 (83)	11 (92)	11 (92)	32 (89)	109 (91)
	Day 8	Abnormal (not CS)	3 (25)	3 (25)	0 (0)	6 (17)	17 (14)
		Normal	9 (75)	9 (75)	12 (100)	30 (83)	103 (86)
	Day 29	Abnormal (not CS)	5 (42)	1 (8)	1 (8)	7 (19)	15 (13)
		Normal	7 (58)	11 (92)	11 (92)	29 (81)	102 (85)
	Day 50	Abnormal (not CS)	2 (17)	0 (0)	0 (0)	2 (6)	10 (8)
		Normal	9 (75)	0 (0)	0 (0)	9 (25)	83 (69)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Leukocytes (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	2 (6)	4 (3)
		Normal	12 (100)	10 (83)	12 (100)	34 (94)	116 (97)
	Day 1	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	6 (5)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 22 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Leukocytes (Blood) [10^9/L]	Day 1	Normal	11 (92)	11 (92)	12 (100)	34 (94)	113 (94)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Day 2	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (6)	8 (7)
		Normal	12 (100)	11 (92)	11 (92)	34 (94)	112 (93)
	Day 8	Abnormal (not CS)	0 (0)	1 (8)	2 (17)	3 (8)	13 (11)
		Normal	12 (100)	11 (92)	10 (83)	33 (92)	107 (89)
	Day 29	Abnormal (not CS)	1 (8)	3 (25)	1 (8)	5 (14)	13 (11)
		Normal	11 (92)	9 (75)	11 (92)	31 (86)	104 (87)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	8 (7)
		Normal	11 (92)	0 (0)	0 (0)	11 (31)	86 (72)
Lymphocytes (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	8 (7)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	112 (93)
	Day 1	Abnormal (not CS)	1 (8)	2 (17)	0 (0)	3 (8)	8 (7)
		Normal	10 (83)	8 (67)	12 (100)	30 (83)	109 (91)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 23 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Lymphocytes (Blood) [10^9/L]	Day 2	Abnormal (not CS)	7 (58)	10 (83)	11 (92)	28 (78)	79 (66)
		Normal	5 (42)	2 (17)	1 (8)	8 (22)	41 (34)
	Day 8	Abnormal (not CS)	1 (8)	3 (25)	1 (8)	5 (14)	9 (8)
		Normal	11 (92)	9 (75)	11 (92)	31 (86)	111 (93)
	Day 29	CS abnormal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Abnormal (not CS)	1 (8)	2 (17)	0 (0)	3 (8)	6 (5)
		Normal	11 (92)	9 (75)	12 (100)	32 (89)	107 (89)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		Normal	11 (92)	0 (0)	0 (0)	11 (31)	90 (75)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Lymphocytes (Blood Smear) [10^9/L]	Day 1	Missing	0 (0)	2 (17)	0 (0)	2 (6)	2 (2)
	Day 29	Missing	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
Lymphocytes/Leukocytes (Blood) [%]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	117 (98)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 24 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Lymphocytes/Leukocytes (Blood) [%]	Day 1	Normal	11 (92)	10 (83)	12 (100)	33 (92)	115 (96)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Day 2	Abnormal (not CS)	3 (25)	5 (42)	10 (83)	18 (50)	58 (48)
		Normal	9 (75)	7 (58)	2 (17)	18 (50)	62 (52)
	Day 8	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	3 (8)	10 (8)
		Normal	11 (92)	11 (92)	11 (92)	33 (92)	110 (92)
	Day 29	Abnormal (not CS)	2 (17)	0 (0)	2 (17)	4 (11)	11 (9)
		Normal	10 (83)	11 (92)	10 (83)	31 (86)	103 (86)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
		Normal	11 (92)	0 (0)	0 (0)	11 (31)	92 (77)
Lymphocytes/Leukocytes (Blood Smear) [%]	Day 1	Normal	0 (0)	2 (17)	0 (0)	2 (6)	2 (2)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Monocytes (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 25 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Monocytes (Blood) [10^9/L]	Day 1	Normal	11 (92)	10 (83)	12 (100)	33 (92)	117 (98)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Day 2	Abnormal (not CS)	1 (8)	1 (8)	2 (17)	4 (11)	14 (12)
		Normal	11 (92)	11 (92)	10 (83)	32 (89)	106 (88)
	Day 8	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (6)	5 (4)
		Normal	12 (100)	11 (92)	11 (92)	34 (94)	115 (96)
	Day 29	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
		Normal	12 (100)	10 (83)	12 (100)	34 (94)	113 (94)
	Day 50	Normal	12 (100)	0 (0)	0 (0)	12 (33)	94 (78)
Monocytes (Blood Smear) [10^9/L]	Day 1	Missing	0 (0)	2 (17)	0 (0)	2 (6)	2 (2)
	Day 29	Missing	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
Monocytes/Leukocytes (Blood) [%]	Day -30 to 0	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (6)	4 (3)
		Normal	11 (92)	11 (92)	12 (100)	34 (94)	116 (97)
	Day 1	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
		Normal	11 (92)	9 (75)	12 (100)	32 (89)	114 (95)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 26 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Monocytes/Leukocytes (Blood) [%]	Day 1	Missing	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Day 2	Abnormal (not CS)	8 (67)	5 (42)	6 (50)	19 (53)	51 (43)
		Normal	4 (33)	7 (58)	6 (50)	17 (47)	69 (58)
	Day 8	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
		Normal	12 (100)	11 (92)	12 (100)	35 (97)	117 (98)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	11 (92)	12 (100)	35 (97)	113 (94)
	Day 50	Abnormal (not CS)	3 (25)	0 (0)	0 (0)	3 (8)	9 (8)
		Normal	8 (67)	0 (0)	0 (0)	8 (22)	84 (70)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Monocytes/Leukocytes (Blood Smear) [%]	Day 1	Normal	0 (0)	2 (17)	0 (0)	2 (6)	2 (2)
	Day 29	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
		Normal	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Neutrophils (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
		Normal	12 (100)	11 (92)	12 (100)	35 (97)	118 (98)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 27 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Neutrophils (Blood) [10^9/L]	Day 1	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	6 (5)
		Normal	11 (92)	10 (83)	11 (92)	32 (89)	111 (93)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	117 (98)
	Day 8	Abnormal (not CS)	2 (17)	0 (0)	3 (25)	5 (14)	11 (9)
		Normal	10 (83)	12 (100)	9 (75)	31 (86)	109 (91)
	Day 29	Abnormal (not CS)	1 (8)	1 (8)	2 (17)	4 (11)	10 (8)
		Normal	11 (92)	10 (83)	10 (83)	31 (86)	104 (87)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	5 (4)
		Normal	11 (92)	0 (0)	0 (0)	11 (31)	89 (74)
Neutrophils (Blood Smear) [10^9/L]	Day 1	Missing	0 (0)	2 (17)	0 (0)	2 (6)	2 (2)
	Day 29	Missing	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
Neutrophils/Leukocytes (Blood) [%]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	116 (97)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 28 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Neutrophils/Leukocytes (Blood) [%]	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	11 (92)	10 (83)	12 (100)	33 (92)	115 (96)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Day 2	Abnormal (not CS)	0 (0)	1 (8)	2 (17)	3 (8)	19 (16)
		Normal	12 (100)	11 (92)	10 (83)	33 (92)	101 (84)
	Day 8	Abnormal (not CS)	1 (8)	1 (8)	2 (17)	4 (11)	8 (7)
		Normal	11 (92)	11 (92)	10 (83)	32 (89)	112 (93)
	Day 29	Abnormal (not CS)	2 (17)	1 (8)	1 (8)	4 (11)	10 (8)
		Normal	10 (83)	10 (83)	11 (92)	31 (86)	104 (87)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
		Normal	11 (92)	0 (0)	0 (0)	11 (31)	92 (77)
Neutrophils/Leukocytes (Blood Smear) [%]	Day 1	Normal	0 (0)	2 (17)	0 (0)	2 (6)	2 (2)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Platelets [10^9/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	4 (3)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 29 of 30)

Table 14.3.2-2.5.1-1: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Platelets [10^9/L]	Day -30 to 0	Normal	11 (92)	12 (100)	11 (92)	34 (94)	116 (97)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	4 (3)
		Normal	10 (83)	12 (100)	12 (100)	34 (94)	115 (96)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Day 2	Abnormal (not CS)	2 (17)	0 (0)	1 (8)	3 (8)	7 (6)
		Normal	10 (83)	12 (100)	11 (92)	33 (92)	113 (94)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	5 (4)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	115 (96)
	Day 29	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (6)	7 (6)
		Normal	12 (100)	11 (92)	11 (92)	34 (94)	110 (92)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	4 (3)
		Normal	11 (92)	0 (0)	0 (0)	11 (31)	90 (75)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 30 of 30)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Alanine Aminotransferase [U/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	83 (99)
	Day 29	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	4 (33)	0 (0)	5 (6)
		Normal	12 (100)	11 (92)	11 (92)	11 (92)	12 (100)	7 (58)	12 (100)	76 (90)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	82 (98)
Albumin [g/L]	Day -30 to 0	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 1	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 2	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 1 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Albumin [g/L]	Day 8	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 29	Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	81 (96)
	Day 50	Normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	82 (98)
Alkaline Phosphatase [U/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	12 (100)	12 (100)	10 (83)	12 (100)	12 (100)	12 (100)	12 (100)	82 (98)
	Day 1	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	4 (5)
		Normal	11 (92)	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	80 (95)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	12 (100)	12 (100)	10 (83)	12 (100)	12 (100)	12 (100)	12 (100)	82 (98)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	10 (83)	11 (92)	12 (100)	11 (92)	12 (100)	80 (95)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	11 (92)	12 (100)	10 (83)	12 (100)	12 (100)	12 (100)	12 (100)	81 (96)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 2 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Amylase [U/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	4 (5)
		Normal	12 (100)	12 (100)	11 (92)	11 (92)	11 (92)	11 (92)	12 (100)	80 (95)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	0 (0)	2 (17)	2 (17)	0 (0)	6 (7)
		Normal	12 (100)	12 (100)	10 (83)	12 (100)	10 (83)	10 (83)	12 (100)	78 (93)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	3 (25)	0 (0)	2 (17)	1 (8)	0 (0)	6 (7)
		Normal	12 (100)	12 (100)	9 (75)	12 (100)	10 (83)	11 (92)	12 (100)	78 (93)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	4 (33)	1 (8)	2 (17)	1 (8)	0 (0)	9 (11)
		Normal	11 (92)	12 (100)	8 (67)	11 (92)	10 (83)	11 (92)	12 (100)	75 (89)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	1 (8)	3 (4)
		Normal	12 (100)	12 (100)	11 (92)	11 (92)	10 (83)	11 (92)	11 (92)	78 (93)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	1 (8)	4 (5)
		Normal	11 (92)	12 (100)	10 (83)	12 (100)	11 (92)	11 (92)	11 (92)	78 (93)
Aspartate Aminotransferase [U/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	83 (99)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 3 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Aspartate Aminotransferase [U/L]	Day 1	Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	0 (0)	3 (4)
		Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	8 (67)	12 (100)	78 (93)
	Day 50	Normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	82 (98)
Bilirubin (Serum) [µmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	3 (4)
		Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	12 (100)	11 (92)	81 (96)
	Day 1	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (17)	4 (5)
		Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	12 (100)	10 (83)	80 (95)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 4 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Bilirubin (Serum) [µmol/L]	Day 8	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	3 (4)
		Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	9 (75)	78 (93)
	Day 50	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	3 (4)
		Normal	11 (92)	11 (92)	11 (92)	11 (92)	12 (100)	12 (100)	11 (92)	79 (94)
C Reactive Protein [mg/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 2	CS abnormal	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
		Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (8)	2 (17)	5 (42)	8 (67)	17 (20)
		Normal	12 (100)	12 (100)	11 (92)	11 (92)	9 (75)	6 (50)	4 (33)	65 (77)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 29	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	4 (5)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 5 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
C Reactive Protein [mg/L]	Day 29	Normal	12 (100)	10 (83)	11 (92)	11 (92)	12 (100)	9 (75)	12 (100)	77 (92)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	82 (98)
Calcium [mmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	2 (17)	1 (8)	1 (8)	0 (0)	0 (0)	5 (6)
		Normal	12 (100)	11 (92)	10 (83)	11 (92)	11 (92)	12 (100)	12 (100)	79 (94)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	4 (5)
		Normal	11 (92)	12 (100)	10 (83)	12 (100)	12 (100)	12 (100)	11 (92)	80 (95)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 8	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	12 (100)	11 (92)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	82 (98)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	10 (83)	11 (92)	12 (100)	11 (92)	12 (100)	80 (95)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	0 (0)	3 (4)
		Normal	11 (92)	12 (100)	10 (83)	12 (100)	11 (92)	11 (92)	12 (100)	79 (94)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 6 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Creatinine [µmol/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	2 (17)	0 (0)	2 (17)	1 (8)	6 (7)
		Normal	11 (92)	12 (100)	12 (100)	10 (83)	12 (100)	10 (83)	11 (92)	78 (93)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	3 (4)
		Normal	11 (92)	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	12 (100)	81 (96)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 8	Abnormal (not CS)	4 (33)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	6 (7)
		Normal	8 (67)	12 (100)	11 (92)	11 (92)	12 (100)	12 (100)	12 (100)	78 (93)
	Day 29	Abnormal (not CS)	2 (17)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	5 (6)
		Normal	10 (83)	12 (100)	10 (83)	10 (83)	12 (100)	11 (92)	11 (92)	76 (90)
	Day 50	Abnormal (not CS)	4 (33)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	5 (6)
		Normal	7 (58)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	11 (92)	77 (92)
Ferritin [µg/L]	Day -30 to 0	Abnormal (not CS)	3 (25)	2 (17)	5 (42)	1 (8)	1 (8)	1 (8)	0 (0)	13 (15)
		Normal	9 (75)	10 (83)	7 (58)	11 (92)	11 (92)	11 (92)	12 (100)	71 (85)
	Day 1	Abnormal (not CS)	3 (25)	3 (25)	4 (33)	1 (8)	0 (0)	1 (8)	1 (8)	13 (15)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 7 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Ferritin [µg/L]	Day 1	Normal	9 (75)	9 (75)	8 (67)	11 (92)	12 (100)	11 (92)	11 (92)	71 (85)
	Day 2	Abnormal (not CS)	3 (25)	3 (25)	4 (33)	1 (8)	0 (0)	0 (0)	1 (8)	12 (14)
		Normal	9 (75)	9 (75)	8 (67)	11 (92)	12 (100)	12 (100)	11 (92)	72 (86)
	Day 8	Abnormal (not CS)	3 (25)	5 (42)	3 (25)	1 (8)	0 (0)	0 (0)	1 (8)	13 (15)
		Normal	9 (75)	7 (58)	9 (75)	11 (92)	12 (100)	12 (100)	11 (92)	71 (85)
	Day 29	Abnormal (not CS)	3 (25)	4 (33)	4 (33)	0 (0)	1 (8)	0 (0)	1 (8)	13 (15)
		Normal	9 (75)	8 (67)	7 (58)	11 (92)	11 (92)	11 (92)	11 (92)	68 (81)
	Day 50	Abnormal (not CS)	3 (25)	3 (25)	3 (25)	3 (25)	2 (17)	2 (17)	0 (0)	16 (19)
		Normal	8 (67)	9 (75)	8 (67)	9 (75)	10 (83)	10 (83)	12 (100)	66 (79)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Follicle Stimulating Hormone [IU/L]	Day -30 to 0	Normal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Missing	4 (33)	4 (33)	3 (25)	4 (33)	1 (8)	0 (0)	0 (0)	16 (19)
Gamma Glutamyl Transferase [U/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	3 (4)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	10 (83)	81 (96)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	3 (4)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 8 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Gamma Glutamyl Transferase [U/L]	Day 1	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	10 (83)	81 (96)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	3 (4)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	10 (83)	81 (96)
	Day 8	CS abnormal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (1)
		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	11 (92)	82 (98)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	1 (8)	3 (4)
		Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	9 (75)	11 (92)	78 (93)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
		Normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	11 (92)	11 (92)	80 (95)
Glucose (Blood) [mmol/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	5 (42)	4 (33)	7 (58)	4 (33)	3 (25)	5 (42)	29 (35)
		Normal	11 (92)	7 (58)	8 (67)	5 (42)	8 (67)	9 (75)	7 (58)	55 (65)
	Day 1	Abnormal (not CS)	0 (0)	4 (33)	3 (25)	2 (17)	3 (25)	1 (8)	3 (25)	16 (19)
		Normal	12 (100)	8 (67)	9 (75)	10 (83)	9 (75)	11 (92)	9 (75)	68 (81)
	Day 2	Abnormal (not CS)	1 (8)	3 (25)	2 (17)	2 (17)	2 (17)	1 (8)	5 (42)	16 (19)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 9 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Glucose (Blood) [mmol/L]	Day 2	Normal	11 (92)	9 (75)	10 (83)	10 (83)	10 (83)	11 (92)	7 (58)	68 (81)
	Day 8	Abnormal (not CS)	3 (25)	3 (25)	2 (17)	5 (42)	3 (25)	3 (25)	3 (25)	22 (26)
		Normal	9 (75)	9 (75)	10 (83)	7 (58)	9 (75)	9 (75)	9 (75)	62 (74)
	Day 29	Abnormal (not CS)	1 (8)	4 (33)	3 (25)	2 (17)	3 (25)	1 (8)	2 (17)	16 (19)
		Normal	11 (92)	8 (67)	8 (67)	9 (75)	9 (75)	10 (83)	10 (83)	65 (77)
	Day 50	Abnormal (not CS)	3 (25)	3 (25)	5 (42)	5 (42)	5 (42)	5 (42)	1 (8)	27 (32)
		Normal	8 (67)	9 (75)	6 (50)	7 (58)	7 (58)	7 (58)	11 (92)	55 (65)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Lipase [U/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	0 (0)	4 (5)
		Normal	11 (92)	12 (100)	11 (92)	12 (100)	11 (92)	11 (92)	12 (100)	80 (95)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	0 (0)	4 (5)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	9 (75)	12 (100)	80 (95)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	0 (0)	1 (8)	2 (17)	0 (0)	5 (6)
		Normal	11 (92)	12 (100)	11 (92)	12 (100)	11 (92)	10 (83)	12 (100)	79 (94)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	1 (8)	4 (5)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 10 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Lipase [U/L]	Day 8	Normal	12 (100)	12 (100)	11 (92)	12 (100)	11 (92)	11 (92)	11 (92)	80 (95)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (17)	0 (0)	2 (17)	1 (8)	7 (8)
		Normal	11 (92)	12 (100)	10 (83)	9 (75)	12 (100)	9 (75)	11 (92)	74 (88)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	0 (0)	1 (8)	2 (17)	0 (0)	5 (6)
		Normal	10 (83)	12 (100)	10 (83)	12 (100)	11 (92)	10 (83)	12 (100)	77 (92)
Potassium [mmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	12 (100)	12 (100)	82 (98)
	Day 1	Abnormal (not CS)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	3 (4)
		Normal	10 (83)	12 (100)	11 (92)	12 (100)	12 (100)	11 (92)	12 (100)	80 (95)
		Missing	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	3 (4)
		Normal	11 (92)	12 (100)	10 (83)	12 (100)	12 (100)	12 (100)	12 (100)	81 (96)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 11 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Potassium [mmol/L]	Day 29	Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	10 (83)	11 (92)	79 (94)
	Day 50	Abnormal (not CS)	0 (0)	1 (8)	3 (25)	1 (8)	0 (0)	2 (17)	1 (8)	8 (10)
		Normal	11 (92)	11 (92)	8 (67)	11 (92)	12 (100)	10 (83)	11 (92)	74 (88)
Sodium [mmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	3 (4)
		Normal	11 (92)	12 (100)	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	81 (96)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (17)	4 (5)
		Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	12 (100)	10 (83)	80 (95)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	10 (83)	11 (92)	12 (100)	11 (92)	12 (100)	80 (95)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
		Normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	11 (92)	12 (100)	81 (96)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 12 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Urea Nitrogen [mmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	2 (17)	5 (6)
		Normal	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	10 (83)	10 (83)	79 (94)
	Day 1	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	0 (0)	4 (5)
		Normal	12 (100)	11 (92)	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	80 (95)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	2 (17)	1 (8)	3 (25)	3 (25)	10 (12)
		Normal	12 (100)	12 (100)	11 (92)	10 (83)	11 (92)	9 (75)	9 (75)	74 (88)
	Day 8	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	5 (6)
		Normal	12 (100)	11 (92)	11 (92)	11 (92)	11 (92)	11 (92)	12 (100)	79 (94)
	Day 29	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (17)	1 (8)	5 (6)
		Normal	12 (100)	11 (92)	10 (83)	11 (92)	12 (100)	9 (75)	11 (92)	76 (90)
	Day 50	Abnormal (not CS)	2 (17)	1 (8)	2 (17)	0 (0)	0 (0)	1 (8)	2 (17)	8 (10)
		Normal	9 (75)	11 (92)	9 (75)	12 (100)	12 (100)	11 (92)	10 (83)	74 (88)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 13 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Alanine Aminotransferase [U/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	118 (98)
	Day 29	Abnormal (not CS)	0 (0)	1 (8)	3 (25)	4 (11)	9 (8)
		Normal	12 (100)	11 (92)	9 (75)	32 (89)	108 (90)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
		Normal	11 (92)	0 (0)	0 (0)	11 (31)	93 (78)
Albumin [g/L]	Day -30 to 0	Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	Day 1	Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	Day 2	Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 14 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Albumin [g/L]	Day 8	Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	Day 29	Normal	12 (100)	12 (100)	12 (100)	36 (100)	117 (98)
	Day 50	Normal	12 (100)	0 (0)	0 (0)	12 (33)	94 (78)
Alkaline Phosphatase [U/L]	Day -30 to 0	Abnormal (not CS)	2 (17)	1 (8)	0 (0)	3 (8)	5 (4)
		Normal	10 (83)	11 (92)	12 (100)	33 (92)	115 (96)
	Day 1	Abnormal (not CS)	2 (17)	1 (8)	0 (0)	3 (8)	7 (6)
		Normal	10 (83)	11 (92)	12 (100)	33 (92)	113 (94)
	Day 2	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (6)	4 (3)
		Normal	11 (92)	11 (92)	12 (100)	34 (94)	116 (97)
	Day 8	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (6)	3 (3)
		Normal	11 (92)	11 (92)	12 (100)	34 (94)	117 (98)
	Day 29	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
		Normal	12 (100)	11 (92)	12 (100)	35 (97)	115 (96)
	Day 50	Abnormal (not CS)	2 (17)	0 (0)	0 (0)	2 (6)	3 (3)
		Normal	10 (83)	0 (0)	0 (0)	10 (28)	91 (76)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 15 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Amylase [U/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	3 (8)	7 (6)
		Normal	11 (92)	11 (92)	11 (92)	33 (92)	113 (94)
	Day 1	Abnormal (not CS)	1 (8)	1 (8)	3 (25)	5 (14)	11 (9)
		Normal	11 (92)	11 (92)	9 (75)	31 (86)	109 (91)
	Day 2	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	3 (8)	9 (8)
		Normal	11 (92)	11 (92)	11 (92)	33 (92)	111 (93)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	3 (25)	4 (11)	13 (11)
		Normal	11 (92)	12 (100)	9 (75)	32 (89)	107 (89)
	Day 29	Abnormal (not CS)	2 (17)	1 (8)	2 (17)	5 (14)	8 (7)
		Normal	10 (83)	11 (92)	10 (83)	31 (86)	109 (91)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	5 (4)
		Normal	11 (92)	0 (0)	0 (0)	11 (31)	89 (74)
Aspartate Aminotransferase [U/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 16 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Aspartate Aminotransferase [U/L]	Day 1	Normal	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
		Normal	12 (100)	12 (100)	10 (83)	34 (94)	118 (98)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	113 (94)
	Day 50	Normal	12 (100)	0 (0)	0 (0)	12 (33)	94 (78)
Bilirubin (Serum) [µmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	116 (97)
	Day 1	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (6)	3 (3)
		Normal	12 (100)	11 (92)	11 (92)	34 (94)	117 (98)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	5 (4)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	115 (96)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 17 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Bilirubin (Serum) [µmol/L]	Day 8	Normal	12 (100)	12 (100)	11 (92)	35 (97)	119 (99)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	113 (94)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		Normal	12 (100)	0 (0)	0 (0)	12 (33)	91 (76)
C Reactive Protein [mg/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	119 (99)
	Day 2	CS abnormal	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Abnormal (not CS)	2 (17)	3 (25)	5 (42)	10 (28)	27 (23)
		Normal	10 (83)	9 (75)	7 (58)	26 (72)	91 (76)
	Day 8	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (6)	2 (2)
		Normal	11 (92)	11 (92)	12 (100)	34 (94)	118 (98)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	5 (4)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 18 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
C Reactive Protein [mg/L]	Day 29	Normal	11 (92)	12 (100)	12 (100)	35 (97)	112 (93)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
		Normal	11 (92)	0 (0)	0 (0)	11 (31)	93 (78)
Calcium [mmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	6 (5)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	114 (95)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	116 (97)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	118 (98)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	116 (97)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		Normal	12 (100)	0 (0)	0 (0)	12 (33)	91 (76)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 19 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Creatinine [µmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	2 (6)	8 (7)
		Normal	12 (100)	10 (83)	12 (100)	34 (94)	112 (93)
	Day 1	Abnormal (not CS)	2 (17)	0 (0)	0 (0)	2 (6)	5 (4)
		Normal	10 (83)	12 (100)	12 (100)	34 (94)	115 (96)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	118 (98)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	7 (6)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	113 (94)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	6 (5)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	111 (93)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
		Normal	12 (100)	0 (0)	0 (0)	12 (33)	89 (74)
Ferritin [µg/L]	Day -30 to 0	Abnormal (not CS)	2 (17)	0 (0)	1 (8)	3 (8)	16 (13)
		Normal	10 (83)	12 (100)	11 (92)	33 (92)	104 (87)
	Day 1	Abnormal (not CS)	2 (17)	0 (0)	1 (8)	3 (8)	16 (13)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 20 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Ferritin [µg/L]	Day 1	Normal	10 (83)	12 (100)	11 (92)	33 (92)	104 (87)
	Day 2	Abnormal (not CS)	2 (17)	0 (0)	2 (17)	4 (11)	16 (13)
		Normal	10 (83)	12 (100)	10 (83)	32 (89)	104 (87)
	Day 8	Abnormal (not CS)	2 (17)	0 (0)	3 (25)	5 (14)	18 (15)
		Normal	10 (83)	12 (100)	9 (75)	31 (86)	102 (85)
	Day 29	Abnormal (not CS)	2 (17)	0 (0)	3 (25)	5 (14)	18 (15)
		Normal	10 (83)	12 (100)	9 (75)	31 (86)	99 (83)
	Day 50	Abnormal (not CS)	3 (25)	0 (0)	0 (0)	3 (8)	19 (16)
		Normal	8 (67)	0 (0)	0 (0)	8 (22)	74 (62)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Follicle Stimulating Hormone [IU/L]	Day -30 to 0	Normal	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
		Missing	2 (17)	10 (83)	5 (42)	17 (47)	33 (28)
Gamma Glutamyl Transferase [U/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	116 (97)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 21 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Gamma Glutamyl Transferase [U/L]	Day 1	Normal	12 (100)	12 (100)	11 (92)	35 (97)	116 (97)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	116 (97)
	Day 8	CS abnormal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	117 (98)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	2 (6)	5 (4)
		Normal	12 (100)	12 (100)	10 (83)	34 (94)	112 (93)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	12 (100)	0 (0)	0 (0)	12 (33)	92 (77)
Glucose (Blood) [mmol/L]	Day -30 to 0	Abnormal (not CS)	6 (50)	10 (83)	7 (58)	23 (64)	52 (43)
		Normal	6 (50)	2 (17)	5 (42)	13 (36)	68 (57)
	Day 1	Abnormal (not CS)	4 (33)	5 (42)	4 (33)	13 (36)	29 (24)
		Normal	8 (67)	7 (58)	8 (67)	23 (64)	91 (76)
	Day 2	Abnormal (not CS)	5 (42)	8 (67)	6 (50)	19 (53)	35 (29)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 22 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Glucose (Blood) [mmol/L]	Day 2	Normal	7 (58)	4 (33)	6 (50)	17 (47)	85 (71)
	Day 8	Abnormal (not CS)	3 (25)	4 (33)	4 (33)	11 (31)	33 (28)
		Normal	9 (75)	8 (67)	8 (67)	25 (69)	87 (73)
	Day 29	Abnormal (not CS)	4 (33)	6 (50)	3 (25)	13 (36)	29 (24)
		Normal	8 (67)	6 (50)	9 (75)	23 (64)	88 (73)
	Day 50	Abnormal (not CS)	4 (33)	0 (0)	0 (0)	4 (11)	31 (26)
		Normal	7 (58)	0 (0)	0 (0)	7 (19)	62 (52)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Lipase [U/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	3 (8)	7 (6)
		Normal	11 (92)	11 (92)	11 (92)	33 (92)	113 (94)
	Day 1	Abnormal (not CS)	0 (0)	3 (25)	1 (8)	4 (11)	8 (7)
		Normal	12 (100)	9 (75)	11 (92)	32 (89)	112 (93)
	Day 2	Abnormal (not CS)	0 (0)	3 (25)	2 (17)	5 (14)	10 (8)
		Normal	12 (100)	9 (75)	10 (83)	31 (86)	110 (92)
	Day 8	Abnormal (not CS)	0 (0)	2 (17)	1 (8)	3 (8)	7 (6)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 23 of 26)

Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Lipase [U/L]	Day 8	Normal	12 (100)	10 (83)	11 (92)	33 (92)	113 (94)
	Day 29	Abnormal (not CS)	1 (8)	3 (25)	2 (17)	6 (17)	13 (11)
		Normal	11 (92)	9 (75)	10 (83)	30 (83)	104 (87)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
		Normal	12 (100)	0 (0)	0 (0)	12 (33)	89 (74)
Potassium [mmol/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	117 (98)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	4 (3)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	115 (96)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	4 (3)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	116 (97)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	118 (98)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

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Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Potassium [mmol/L]	Day 29	Normal	12 (100)	12 (100)	11 (92)	35 (97)	114 (95)
	Day 50	Abnormal (not CS)	3 (25)	0 (0)	0 (0)	3 (8)	11 (9)
		Normal	9 (75)	0 (0)	0 (0)	9 (25)	83 (69)
Sodium [mmol/L]	Day -30 to 0	Abnormal (not CS)	2 (17)	0 (0)	2 (17)	4 (11)	5 (4)
		Normal	10 (83)	12 (100)	10 (83)	32 (89)	115 (96)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	2 (6)	5 (4)
		Normal	12 (100)	12 (100)	10 (83)	34 (94)	115 (96)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	6 (5)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	114 (95)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	118 (98)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	115 (96)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
		Normal	11 (92)	0 (0)	0 (0)	11 (31)	92 (77)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

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Table 14.3.2-2.5.2-1: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Urea Nitrogen [mmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	3 (25)	0 (0)	3 (8)	8 (7)
		Normal	12 (100)	9 (75)	12 (100)	33 (92)	112 (93)
	Day 1	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (6)	6 (5)
		Normal	11 (92)	11 (92)	12 (100)	34 (94)	114 (95)
	Day 2	Abnormal (not CS)	2 (17)	0 (0)	0 (0)	2 (6)	12 (10)
		Normal	10 (83)	12 (100)	12 (100)	34 (94)	108 (90)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	6 (5)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	114 (95)
	Day 29	Abnormal (not CS)	1 (8)	2 (17)	1 (8)	4 (11)	9 (8)
		Normal	11 (92)	10 (83)	11 (92)	32 (89)	108 (90)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	9 (8)
		Normal	11 (92)	0 (0)	0 (0)	11 (31)	85 (71)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

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Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Bacteria [/HPF]	Day -30 to 0	Abnormal (not CS)	2 (17)	0 (0)	3 (25)	0 (0)	1 (8)	3 (25)	0 (0)	9 (11)
		Normal	2 (17)	4 (33)	3 (25)	3 (25)	1 (8)	3 (25)	2 (17)	18 (21)
		Missing	1 (8)	2 (17)	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	6 (7)
	Day 1	Abnormal (not CS)	2 (17)	0 (0)	1 (8)	2 (17)	0 (0)	2 (17)	1 (8)	8 (10)
		Normal	1 (8)	1 (8)	2 (17)	0 (0)	2 (17)	1 (8)	3 (25)	10 (12)
		Missing	3 (25)	2 (17)	2 (17)	0 (0)	1 (8)	1 (8)	1 (8)	10 (12)
	Day 2	Abnormal (not CS)	2 (17)	2 (17)	0 (0)	2 (17)	1 (8)	1 (8)	2 (17)	10 (12)
		Normal	3 (25)	1 (8)	1 (8)	0 (0)	1 (8)	3 (25)	2 (17)	11 (13)
		Missing	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	2 (17)	1 (8)	6 (7)
	Day 8	Abnormal (not CS)	4 (33)	2 (17)	2 (17)	0 (0)	3 (25)	4 (33)	1 (8)	16 (19)
		Normal	1 (8)	1 (8)	2 (17)	0 (0)	0 (0)	2 (17)	0 (0)	6 (7)
		Missing	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
	Day 29	Abnormal (not CS)	5 (42)	3 (25)	1 (8)	1 (8)	1 (8)	2 (17)	0 (0)	13 (15)
		Normal	0 (0)	2 (17)	3 (25)	1 (8)	2 (17)	1 (8)	4 (33)	13 (15)
		Missing	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

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Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Bacteria [/HPF]	Day 50	Abnormal (not CS)	2 (17)	2 (17)	1 (8)	2 (17)	2 (17)	2 (17)	1 (8)	12 (14)
		Normal	2 (17)	2 (17)	2 (17)	1 (8)	0 (0)	4 (33)	1 (8)	12 (14)
		Missing	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	6 (7)
Bilirubin (Urine) [µmol/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	2 (17)	0 (0)	6 (7)
		Normal	11 (92)	11 (92)	11 (92)	12 (100)	11 (92)	10 (83)	12 (100)	78 (93)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	1 (8)	0 (0)	1 (8)	0 (0)	4 (5)
		Normal	11 (92)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	80 (95)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	11 (92)	82 (98)
	Day 8	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	3 (25)	1 (8)	5 (6)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	9 (75)	11 (92)	79 (94)
	Day 29	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	2 (17)	1 (8)	4 (5)
		Normal	12 (100)	11 (92)	11 (92)	11 (92)	12 (100)	9 (75)	11 (92)	77 (92)
	Day 50	Abnormal (not CS)	2 (17)	0 (0)	1 (8)	0 (0)	1 (8)	2 (17)	0 (0)	6 (7)
		Normal	9 (75)	12 (100)	11 (92)	12 (100)	11 (92)	10 (83)	12 (100)	77 (92)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

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Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Casts [/HPF]	Day -30 to 0	Normal	4 (33)	4 (33)	6 (50)	3 (25)	2 (17)	6 (50)	2 (17)	27 (32)
		Missing	1 (8)	2 (17)	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	6 (7)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
		Normal	3 (25)	1 (8)	3 (25)	2 (17)	2 (17)	2 (17)	4 (33)	17 (20)
		Missing	3 (25)	2 (17)	2 (17)	0 (0)	1 (8)	1 (8)	1 (8)	10 (12)
	Day 2	Normal	5 (42)	3 (25)	1 (8)	2 (17)	2 (17)	4 (33)	4 (33)	21 (25)
		Missing	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	2 (17)	1 (8)	6 (7)
	Day 8	Normal	4 (33)	3 (25)	4 (33)	0 (0)	3 (25)	6 (50)	1 (8)	21 (25)
		Missing	1 (8)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	5 (6)
	Day 29	Normal	5 (42)	5 (42)	4 (33)	2 (17)	3 (25)	3 (25)	4 (33)	26 (31)
		Missing	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
	Day 50	Normal	4 (33)	4 (33)	3 (25)	3 (25)	2 (17)	6 (50)	2 (17)	24 (29)
		Missing	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	6 (7)
Crystals [/HPF]	Day -30 to 0	Abnormal (not CS)	2 (17)	2 (17)	3 (25)	0 (0)	1 (8)	0 (0)	0 (0)	8 (10)
		Normal	3 (25)	4 (33)	5 (42)	3 (25)	2 (17)	6 (50)	2 (17)	25 (30)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

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Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Crystals [/HPF]	Day 1	Abnormal (not CS)	2 (17)	2 (17)	2 (17)	1 (8)	1 (8)	1 (8)	1 (8)	10 (12)
		Normal	3 (25)	1 (8)	3 (25)	1 (8)	2 (17)	3 (25)	4 (33)	17 (20)
		Missing	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	1 (8)	6 (7)
		Normal	4 (33)	3 (25)	1 (8)	2 (17)	2 (17)	4 (33)	4 (33)	20 (24)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
	Day 8	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	3 (4)
		Normal	4 (33)	3 (25)	4 (33)	0 (0)	3 (25)	6 (50)	1 (8)	21 (25)
		Missing	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 29	Abnormal (not CS)	2 (17)	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	6 (7)
		Normal	3 (25)	4 (33)	4 (33)	2 (17)	3 (25)	3 (25)	4 (33)	23 (27)
		Missing	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 50	Abnormal (not CS)	1 (8)	3 (25)	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	8 (10)
		Normal	4 (33)	2 (17)	3 (25)	3 (25)	2 (17)	6 (50)	2 (17)	22 (26)
Epithelial Cells [/HPF]	Day -30 to 0	Abnormal (not CS)	2 (17)	0 (0)	3 (25)	2 (17)	1 (8)	2 (17)	1 (8)	11 (13)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 4 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Epithelial Cells [/HPF]	Day -30 to 0	Normal	2 (17)	4 (33)	3 (25)	1 (8)	1 (8)	4 (33)	1 (8)	16 (19)
		Missing	1 (8)	2 (17)	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	6 (7)
	Day 1	Abnormal (not CS)	3 (25)	0 (0)	1 (8)	1 (8)	2 (17)	2 (17)	2 (17)	11 (13)
		Normal	1 (8)	1 (8)	2 (17)	1 (8)	0 (0)	1 (8)	2 (17)	8 (10)
		Missing	2 (17)	2 (17)	2 (17)	0 (0)	1 (8)	1 (8)	1 (8)	9 (11)
	Day 2	Abnormal (not CS)	3 (25)	2 (17)	0 (0)	1 (8)	1 (8)	4 (33)	1 (8)	12 (14)
		Normal	2 (17)	1 (8)	1 (8)	1 (8)	1 (8)	1 (8)	3 (25)	10 (12)
		Missing	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	1 (8)	5 (6)
	Day 8	Abnormal (not CS)	4 (33)	1 (8)	4 (33)	0 (0)	3 (25)	0 (0)	1 (8)	13 (15)
		Normal	1 (8)	2 (17)	0 (0)	0 (0)	0 (0)	6 (50)	0 (0)	9 (11)
		Missing	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
	Day 29	Abnormal (not CS)	2 (17)	1 (8)	2 (17)	1 (8)	2 (17)	2 (17)	0 (0)	10 (12)
		Normal	3 (25)	4 (33)	3 (25)	1 (8)	1 (8)	1 (8)	4 (33)	17 (20)
		Missing	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	3 (4)
	Day 50	CS abnormal	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 5 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Epithelial Cells [/HPF]	Day 50	Abnormal (not CS)	2 (17)	2 (17)	1 (8)	2 (17)	1 (8)	3 (25)	1 (8)	12 (14)
		Normal	1 (8)	2 (17)	2 (17)	1 (8)	1 (8)	3 (25)	1 (8)	11 (13)
		Missing	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	6 (7)
Erythrocytes (Urine) [/HPF]	Day -30 to 0	Abnormal (not CS)	2 (17)	1 (8)	2 (17)	0 (0)	1 (8)	0 (0)	1 (8)	7 (8)
		Normal	2 (17)	3 (25)	4 (33)	3 (25)	1 (8)	6 (50)	1 (8)	20 (24)
		Missing	1 (8)	2 (17)	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	6 (7)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	0 (0)	3 (4)
		Normal	3 (25)	1 (8)	3 (25)	1 (8)	1 (8)	2 (17)	4 (33)	15 (18)
		Missing	3 (25)	2 (17)	2 (17)	0 (0)	1 (8)	1 (8)	1 (8)	10 (12)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	3 (4)
		Normal	4 (33)	3 (25)	1 (8)	1 (8)	2 (17)	3 (25)	4 (33)	18 (21)
		Missing	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	2 (17)	1 (8)	6 (7)
	Day 8	Abnormal (not CS)	2 (17)	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	5 (6)
		Normal	2 (17)	1 (8)	4 (33)	0 (0)	3 (25)	5 (42)	1 (8)	16 (19)
		Missing	1 (8)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	5 (6)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 6 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Erythrocytes (Urine) [/HPF]	Day 29	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	3 (25)	0 (0)	7 (8)
		Normal	4 (33)	4 (33)	3 (25)	2 (17)	2 (17)	0 (0)	4 (33)	19 (23)
		Missing	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
	Day 50	Abnormal (not CS)	2 (17)	1 (8)	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	7 (8)
		Normal	2 (17)	3 (25)	2 (17)	2 (17)	1 (8)	5 (42)	2 (17)	17 (20)
		Missing	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	6 (7)
Glucose (Urine)	Day -30 to 0	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 1	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 2	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 8	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 29	Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	81 (96)
	Day 50	Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
Hemoglobin (Urine) [10^6/L]	Day -30 to 0	Abnormal (not CS)	4 (33)	4 (33)	4 (33)	2 (17)	2 (17)	4 (33)	2 (17)	22 (26)
		Normal	8 (67)	8 (67)	8 (67)	10 (83)	10 (83)	8 (67)	10 (83)	62 (74)
	Day 1	Abnormal (not CS)	4 (33)	2 (17)	2 (17)	2 (17)	2 (17)	4 (33)	2 (17)	18 (21)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 7 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Hemoglobin (Urine) [10^6/L]	Day 1	Normal	8 (67)	10 (83)	10 (83)	10 (83)	10 (83)	8 (67)	10 (83)	66 (79)
	Day 2	Abnormal (not CS)	2 (17)	2 (17)	1 (8)	3 (25)	3 (25)	5 (42)	3 (25)	19 (23)
		Normal	10 (83)	10 (83)	11 (92)	9 (75)	9 (75)	7 (58)	9 (75)	65 (77)
	Day 8	Abnormal (not CS)	4 (33)	2 (17)	3 (25)	0 (0)	2 (17)	5 (42)	1 (8)	17 (20)
		Normal	8 (67)	10 (83)	9 (75)	12 (100)	10 (83)	7 (58)	11 (92)	67 (80)
	Day 29	Abnormal (not CS)	1 (8)	4 (33)	3 (25)	1 (8)	2 (17)	3 (25)	1 (8)	15 (18)
		Normal	11 (92)	8 (67)	8 (67)	10 (83)	10 (83)	8 (67)	11 (92)	66 (79)
	Day 50	Abnormal (not CS)	4 (33)	4 (33)	4 (33)	4 (33)	1 (8)	4 (33)	1 (8)	22 (26)
		Normal	7 (58)	8 (67)	8 (67)	8 (67)	11 (92)	8 (67)	11 (92)	61 (73)
Ketones [mmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	0 (0)	4 (33)	0 (0)	1 (8)	7 (8)
		Normal	12 (100)	11 (92)	11 (92)	12 (100)	8 (67)	12 (100)	11 (92)	77 (92)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	3 (4)
		Normal	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	11 (92)	11 (92)	81 (96)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	4 (33)	7 (8)
		Normal	12 (100)	12 (100)	11 (92)	12 (100)	11 (92)	11 (92)	8 (67)	77 (92)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 8 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Ketones [mmol/L]	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	3 (25)	0 (0)	5 (6)
		Normal	12 (100)	12 (100)	12 (100)	11 (92)	11 (92)	9 (75)	12 (100)	79 (94)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	0 (0)	3 (4)
		Normal	12 (100)	12 (100)	11 (92)	10 (83)	12 (100)	9 (75)	12 (100)	78 (93)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	0 (0)	2 (17)	2 (17)	2 (17)	8 (10)
		Normal	10 (83)	12 (100)	11 (92)	12 (100)	10 (83)	10 (83)	10 (83)	75 (89)
Leukocytes (Urine - Dipstick) [10^6/L]	Day -30 to 0	Abnormal (not CS)	3 (25)	1 (8)	5 (42)	1 (8)	1 (8)	4 (33)	0 (0)	15 (18)
		Normal	9 (75)	11 (92)	7 (58)	11 (92)	11 (92)	8 (67)	12 (100)	69 (82)
	Day 1	Abnormal (not CS)	4 (33)	1 (8)	4 (33)	0 (0)	2 (17)	3 (25)	3 (25)	17 (20)
		Normal	8 (67)	11 (92)	8 (67)	12 (100)	10 (83)	9 (75)	9 (75)	67 (80)
	Day 2	Abnormal (not CS)	4 (33)	0 (0)	2 (17)	1 (8)	1 (8)	2 (17)	4 (33)	14 (17)
		Normal	8 (67)	12 (100)	10 (83)	11 (92)	11 (92)	10 (83)	8 (67)	70 (83)
	Day 8	Abnormal (not CS)	3 (25)	3 (25)	4 (33)	0 (0)	1 (8)	5 (42)	1 (8)	17 (20)
		Normal	9 (75)	9 (75)	8 (67)	12 (100)	11 (92)	7 (58)	11 (92)	67 (80)
	Day 29	Abnormal (not CS)	5 (42)	2 (17)	3 (25)	1 (8)	1 (8)	2 (17)	4 (33)	18 (21)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 9 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Leukocytes (Urine - Dipstick) [10^6/L]	Day 29	Normal	7 (58)	10 (83)	8 (67)	10 (83)	11 (92)	9 (75)	8 (67)	63 (75)
	Day 50	CS abnormal	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Abnormal (not CS)	2 (17)	2 (17)	2 (17)	0 (0)	1 (8)	3 (25)	2 (17)	12 (14)
		Normal	8 (67)	10 (83)	10 (83)	12 (100)	11 (92)	9 (75)	10 (83)	70 (83)
Leukocytes (Urine - Microscopy) [/HPF]	Day -30 to 0	Abnormal (not CS)	2 (17)	1 (8)	5 (42)	1 (8)	1 (8)	4 (33)	0 (0)	14 (17)
		Normal	2 (17)	3 (25)	1 (8)	2 (17)	1 (8)	2 (17)	2 (17)	13 (15)
		Missing	1 (8)	2 (17)	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	6 (7)
	Day 1	Abnormal (not CS)	2 (17)	0 (0)	3 (25)	0 (0)	1 (8)	2 (17)	3 (25)	11 (13)
		Normal	1 (8)	1 (8)	1 (8)	2 (17)	1 (8)	1 (8)	1 (8)	8 (10)
		Missing	3 (25)	2 (17)	1 (8)	0 (0)	1 (8)	1 (8)	1 (8)	9 (11)
	Day 2	Abnormal (not CS)	3 (25)	3 (25)	1 (8)	0 (0)	0 (0)	3 (25)	1 (8)	11 (13)
		Normal	2 (17)	0 (0)	0 (0)	2 (17)	2 (17)	1 (8)	3 (25)	10 (12)
		Missing	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	2 (17)	1 (8)	6 (7)
	Day 8	Abnormal (not CS)	3 (25)	1 (8)	5 (42)	0 (0)	1 (8)	3 (25)	1 (8)	14 (17)
		Normal	1 (8)	2 (17)	0 (0)	0 (0)	2 (17)	3 (25)	0 (0)	8 (10)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 10 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Leukocytes (Urine - Microscopy) [/HPF]	Day 8	Missing	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
	Day 29	Abnormal (not CS)	3 (25)	2 (17)	1 (8)	1 (8)	0 (0)	2 (17)	1 (8)	10 (12)
		Normal	2 (17)	3 (25)	3 (25)	1 (8)	3 (25)	1 (8)	3 (25)	16 (19)
		Missing	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
	Day 50	Abnormal (not CS)	2 (17)	2 (17)	2 (17)	3 (25)	1 (8)	1 (8)	1 (8)	12 (14)
		Normal	2 (17)	2 (17)	1 (8)	0 (0)	1 (8)	5 (42)	1 (8)	12 (14)
		Missing	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	6 (7)
Nitrite	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	82 (98)
	Day 1	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	82 (98)
	Day 2	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	82 (98)
	Day 8	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	82 (98)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 11 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Nitrite	Day 29	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	3 (4)
		Normal	12 (100)	10 (83)	11 (92)	11 (92)	12 (100)	10 (83)	12 (100)	78 (93)
	Day 50	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	11 (92)	10 (83)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	81 (96)
pH	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 1	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	0 (0)	1 (8)	4 (5)
		Normal	12 (100)	11 (92)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	80 (95)
	Day 2	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	2 (17)	1 (8)	7 (8)
		Normal	11 (92)	11 (92)	11 (92)	11 (92)	12 (100)	10 (83)	11 (92)	77 (92)
	Day 8	Abnormal (not CS)	1 (8)	2 (17)	0 (0)	2 (17)	1 (8)	1 (8)	1 (8)	8 (10)
		Normal	11 (92)	10 (83)	12 (100)	10 (83)	11 (92)	11 (92)	11 (92)	76 (90)
	Day 29	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	4 (5)
		Normal	12 (100)	10 (83)	11 (92)	10 (83)	12 (100)	11 (92)	11 (92)	77 (92)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	4 (5)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 12 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
pH	Day 50	Normal	10 (83)	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	10 (83)	79 (94)
Protein [mg/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	3 (4)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	81 (96)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	3 (4)
		Normal	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	11 (92)	11 (92)	81 (96)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	2 (2)
		Normal	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	11 (92)	12 (100)	82 (98)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (17)	0 (0)	3 (4)
		Normal	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	10 (83)	12 (100)	81 (96)
	Day 29	Abnormal (not CS)	0 (0)	2 (17)	1 (8)	1 (8)	0 (0)	2 (17)	0 (0)	6 (7)
		Normal	12 (100)	10 (83)	10 (83)	10 (83)	12 (100)	9 (75)	12 (100)	75 (89)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (17)	0 (0)	4 (5)
		Normal	11 (92)	12 (100)	10 (83)	12 (100)	12 (100)	10 (83)	12 (100)	79 (94)
Round Epithelial Cells [/HPF]	Day -30 to 0	Abnormal (not CS)	1 (8)	1 (8)	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	5 (6)
		Normal	3 (25)	3 (25)	4 (33)	3 (25)	2 (17)	6 (50)	1 (8)	22 (26)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 13 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Round Epithelial Cells [/HPF]	Day -30 to 0	Missing	1 (8)	2 (17)	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	6 (7)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	2 (2)
		Normal	3 (25)	1 (8)	3 (25)	1 (8)	2 (17)	2 (17)	4 (33)	16 (19)
		Missing	3 (25)	2 (17)	2 (17)	0 (0)	1 (8)	1 (8)	1 (8)	10 (12)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	5 (42)	3 (25)	1 (8)	2 (17)	2 (17)	4 (33)	4 (33)	21 (25)
		Missing	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	2 (17)	1 (8)	6 (7)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	2 (2)
		Normal	3 (25)	3 (25)	4 (33)	0 (0)	3 (25)	6 (50)	0 (0)	19 (23)
		Missing	1 (8)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	5 (6)
	Day 29	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	5 (42)	4 (33)	4 (33)	2 (17)	3 (25)	3 (25)	4 (33)	25 (30)
		Missing	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	4 (5)
	Day 50	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (17)	1 (8)	5 (6)
		Normal	4 (33)	3 (25)	2 (17)	3 (25)	2 (17)	4 (33)	1 (8)	19 (23)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 14 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Round Epithelial Cells [/HPF]	Day 50	Missing	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	6 (7)
Specific Gravity	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	12 (100)	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	82 (98)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 2	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 8	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 29	Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	81 (96)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	82 (98)
Urobilinogen [µmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 1	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 15 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Younger dose ranging cohorts							
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Urobilinogen [µmol/L]	Day 2	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 8	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	82 (98)
	Day 29	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	11 (92)	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	80 (95)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	82 (98)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 16 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Bacteria [/HPF]	Day -30 to 0	Abnormal (not CS)	1 (8)	7 (58)	3 (25)	11 (31)	20 (17)
		Normal	3 (25)	0 (0)	2 (17)	5 (14)	23 (19)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
	Day 1	Abnormal (not CS)	0 (0)	3 (25)	3 (25)	6 (17)	14 (12)
		Normal	2 (17)	0 (0)	2 (17)	4 (11)	14 (12)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	10 (8)
	Day 2	Abnormal (not CS)	0 (0)	4 (33)	0 (0)	4 (11)	14 (12)
		Normal	5 (42)	0 (0)	4 (33)	9 (25)	20 (17)
		Missing	0 (0)	0 (0)	1 (8)	1 (3)	7 (6)
	Day 8	Abnormal (not CS)	1 (8)	6 (50)	1 (8)	8 (22)	24 (20)
		Normal	3 (25)	0 (0)	4 (33)	7 (19)	13 (11)
		Missing	0 (0)	1 (8)	0 (0)	1 (3)	5 (4)
	Day 29	Abnormal (not CS)	2 (17)	2 (17)	4 (33)	8 (22)	21 (18)
		Normal	2 (17)	5 (42)	2 (17)	9 (25)	22 (18)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	5 (4)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 17 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Bacteria [/HPF]	Day 50	Abnormal (not CS)	2 (17)	0 (0)	0 (0)	2 (6)	14 (12)
		Normal	3 (25)	0 (0)	0 (0)	3 (8)	15 (13)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	7 (6)
Bilirubin (Urine) [µmol/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	3 (25)	0 (0)	4 (11)	10 (8)
		Normal	11 (92)	9 (75)	12 (100)	32 (89)	110 (92)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	5 (4)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	115 (96)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	117 (98)
	Day 8	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	6 (5)
		Normal	12 (100)	11 (92)	12 (100)	35 (97)	114 (95)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	5 (4)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	112 (93)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	7 (6)
		Normal	11 (92)	0 (0)	0 (0)	11 (31)	88 (73)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 18 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Casts [/HPF]	Day -30 to 0	Normal	4 (33)	7 (58)	5 (42)	16 (44)	43 (36)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	2 (17)	3 (25)	5 (42)	10 (28)	27 (23)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	10 (8)
	Day 2	Normal	5 (42)	2 (17)	4 (33)	11 (31)	32 (27)
		Missing	0 (0)	2 (17)	1 (8)	3 (8)	9 (8)
	Day 8	Normal	4 (33)	5 (42)	5 (42)	14 (39)	35 (29)
		Missing	0 (0)	2 (17)	0 (0)	2 (6)	7 (6)
	Day 29	Normal	4 (33)	7 (58)	6 (50)	17 (47)	43 (36)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	5 (4)
	Day 50	Normal	5 (42)	0 (0)	0 (0)	5 (14)	29 (24)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	7 (6)
Crystals [/HPF]	Day -30 to 0	Abnormal (not CS)	1 (8)	5 (42)	0 (0)	6 (17)	14 (12)
		Normal	3 (25)	2 (17)	5 (42)	10 (28)	35 (29)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 19 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Crystals [/HPF]	Day 1	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	11 (9)
		Normal	2 (17)	3 (25)	4 (33)	9 (25)	26 (22)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	2 (6)	8 (7)
		Normal	5 (42)	2 (17)	3 (25)	10 (28)	30 (25)
		Missing	0 (0)	2 (17)	0 (0)	2 (6)	3 (3)
	Day 8	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	2 (6)	5 (4)
		Normal	4 (33)	4 (33)	5 (42)	13 (36)	34 (28)
		Missing	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
	Day 29	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (6)	8 (7)
		Normal	4 (33)	6 (50)	6 (50)	16 (44)	39 (33)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	9 (8)
		Normal	5 (42)	0 (0)	0 (0)	5 (14)	27 (23)
Epithelial Cells [/HPF]	Day -30 to 0	Abnormal (not CS)	0 (0)	3 (25)	2 (17)	5 (14)	16 (13)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 20 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Epithelial Cells [/HPF]	Day -30 to 0	Normal	4 (33)	4 (33)	3 (25)	11 (31)	27 (23)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	12 (10)
		Normal	2 (17)	3 (25)	4 (33)	9 (25)	17 (14)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	9 (8)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	13 (11)
		Normal	5 (42)	2 (17)	3 (25)	10 (28)	20 (17)
		Missing	0 (0)	2 (17)	1 (8)	3 (8)	8 (7)
	Day 8	Abnormal (not CS)	0 (0)	2 (17)	1 (8)	3 (8)	16 (13)
		Normal	4 (33)	3 (25)	4 (33)	11 (31)	20 (17)
		Missing	0 (0)	2 (17)	0 (0)	2 (6)	6 (5)
	Day 29	Abnormal (not CS)	2 (17)	0 (0)	2 (17)	4 (11)	14 (12)
		Normal	2 (17)	7 (58)	4 (33)	13 (36)	30 (25)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	4 (3)
	Day 50	CS abnormal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 21 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Epithelial Cells [/HPF]	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	12 (10)
		Normal	5 (42)	0 (0)	0 (0)	5 (14)	16 (13)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	7 (6)
Erythrocytes (Urine) [/HPF]	Day -30 to 0	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	8 (7)
		Normal	3 (25)	7 (58)	5 (42)	15 (42)	35 (29)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
	Day 1	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	2 (6)	5 (4)
		Normal	2 (17)	1 (8)	5 (42)	8 (22)	23 (19)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	10 (8)
	Day 2	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (6)	5 (4)
		Normal	5 (42)	1 (8)	3 (25)	9 (25)	27 (23)
		Missing	0 (0)	2 (17)	1 (8)	3 (8)	9 (8)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	6 (5)
		Normal	4 (33)	5 (42)	4 (33)	13 (36)	29 (24)
		Missing	0 (0)	2 (17)	0 (0)	2 (6)	7 (6)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 22 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Erythrocytes (Urine) [/HPF]	Day 29	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (6)	9 (8)
		Normal	3 (25)	6 (50)	6 (50)	15 (42)	34 (28)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	5 (4)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	8 (7)
		Normal	4 (33)	0 (0)	0 (0)	4 (11)	21 (18)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	7 (6)
Glucose (Urine)	Day -30 to 0	Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	Day 1	Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	Day 2	Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	Day 8	Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	Day 29	Normal	12 (100)	12 (100)	12 (100)	36 (100)	117 (98)
	Day 50	Normal	12 (100)	0 (0)	0 (0)	12 (33)	95 (79)
Hemoglobin (Urine) [10^6/L]	Day -30 to 0	Abnormal (not CS)	2 (17)	3 (25)	2 (17)	7 (19)	29 (24)
		Normal	10 (83)	9 (75)	10 (83)	29 (81)	91 (76)
	Day 1	Abnormal (not CS)	1 (8)	1 (8)	2 (17)	4 (11)	22 (18)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 23 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Hemoglobin (Urine) [10^6/L]	Day 1	Normal	11 (92)	11 (92)	10 (83)	32 (89)	98 (82)
	Day 2	Abnormal (not CS)	2 (17)	1 (8)	4 (33)	7 (19)	26 (22)
		Normal	10 (83)	11 (92)	8 (67)	29 (81)	94 (78)
	Day 8	Abnormal (not CS)	3 (25)	1 (8)	2 (17)	6 (17)	23 (19)
		Normal	9 (75)	11 (92)	10 (83)	30 (83)	97 (81)
	Day 29	Abnormal (not CS)	3 (25)	4 (33)	2 (17)	9 (25)	24 (20)
		Normal	9 (75)	8 (67)	10 (83)	27 (75)	93 (78)
	Day 50	Abnormal (not CS)	2 (17)	0 (0)	0 (0)	2 (6)	24 (20)
		Normal	10 (83)	0 (0)	0 (0)	10 (28)	71 (59)
Ketones [mmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	8 (7)
		Normal	12 (100)	11 (92)	12 (100)	35 (97)	112 (93)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	117 (98)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	8 (7)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	112 (93)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 24 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Ketones [mmol/L]	Day 8	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	6 (5)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	114 (95)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	4 (3)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	113 (94)
	Day 50	Abnormal (not CS)	2 (17)	0 (0)	0 (0)	2 (6)	10 (8)
		Normal	10 (83)	0 (0)	0 (0)	10 (28)	85 (71)
Leukocytes (Urine - Dipstick) [10^6/L]	Day -30 to 0	Abnormal (not CS)	2 (17)	5 (42)	5 (42)	12 (33)	27 (23)
		Normal	10 (83)	7 (58)	7 (58)	24 (67)	93 (78)
	Day 1	Abnormal (not CS)	1 (8)	2 (17)	4 (33)	7 (19)	24 (20)
		Normal	11 (92)	10 (83)	8 (67)	29 (81)	96 (80)
	Day 2	Abnormal (not CS)	4 (33)	3 (25)	3 (25)	10 (28)	24 (20)
		Normal	8 (67)	9 (75)	9 (75)	26 (72)	96 (80)
	Day 8	Abnormal (not CS)	2 (17)	6 (50)	5 (42)	13 (36)	30 (25)
		Normal	10 (83)	6 (50)	7 (58)	23 (64)	90 (75)
	Day 29	Abnormal (not CS)	3 (25)	5 (42)	6 (50)	14 (39)	32 (27)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 25 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Leukocytes (Urine - Dipstick) [10^6/L]	Day 29	Normal	9 (75)	7 (58)	6 (50)	22 (61)	85 (71)
	Day 50	CS abnormal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Abnormal (not CS)	3 (25)	0 (0)	0 (0)	3 (8)	15 (13)
		Normal	9 (75)	0 (0)	0 (0)	9 (25)	79 (66)
Leukocytes (Urine - Microscopy) [/HPF]	Day -30 to 0	Abnormal (not CS)	1 (8)	2 (17)	3 (25)	6 (17)	20 (17)
		Normal	3 (25)	5 (42)	2 (17)	10 (28)	23 (19)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
	Day 1	Abnormal (not CS)	0 (0)	2 (17)	3 (25)	5 (14)	16 (13)
		Normal	2 (17)	1 (8)	2 (17)	5 (14)	13 (11)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	9 (8)
	Day 2	Abnormal (not CS)	3 (25)	0 (0)	0 (0)	3 (8)	14 (12)
		Normal	2 (17)	2 (17)	4 (33)	8 (22)	18 (15)
		Missing	0 (0)	2 (17)	1 (8)	3 (8)	9 (8)
	Day 8	Abnormal (not CS)	2 (17)	2 (17)	5 (42)	9 (25)	23 (19)
		Normal	2 (17)	3 (25)	0 (0)	5 (14)	13 (11)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 26 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Leukocytes (Urine - Microscopy) [/HPF]	Day 8	Missing	0 (0)	2 (17)	0 (0)	2 (6)	6 (5)
	Day 29	Abnormal (not CS)	4 (33)	3 (25)	4 (33)	11 (31)	21 (18)
		Normal	0 (0)	4 (33)	2 (17)	6 (17)	22 (18)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	5 (4)
	Day 50	Abnormal (not CS)	3 (25)	0 (0)	0 (0)	3 (8)	15 (13)
		Normal	2 (17)	0 (0)	0 (0)	2 (6)	14 (12)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	7 (6)
Nitrite	Day -30 to 0	Abnormal (not CS)	0 (0)	4 (33)	0 (0)	4 (11)	6 (5)
		Normal	12 (100)	8 (67)	12 (100)	32 (89)	114 (95)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	118 (98)
	Day 2	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
		Normal	12 (100)	11 (92)	12 (100)	35 (97)	117 (98)
	Day 8	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	2 (6)	4 (3)
		Normal	12 (100)	10 (83)	12 (100)	34 (94)	116 (97)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 27 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Nitrite	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	114 (95)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	12 (100)	0 (0)	0 (0)	12 (33)	93 (78)
pH	Day -30 to 0	Abnormal (not CS)	3 (25)	1 (8)	1 (8)	5 (14)	6 (5)
		Normal	9 (75)	11 (92)	11 (92)	31 (86)	114 (95)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	5 (4)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	115 (96)
	Day 2	Abnormal (not CS)	4 (33)	4 (33)	3 (25)	11 (31)	18 (15)
		Normal	8 (67)	8 (67)	9 (75)	25 (69)	102 (85)
	Day 8	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	3 (8)	11 (9)
		Normal	11 (92)	11 (92)	11 (92)	33 (92)	109 (91)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	5 (4)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	112 (93)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 28 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
pH	Day 50	Normal	12 (100)	0 (0)	0 (0)	12 (33)	91 (76)
Protein [mg/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	2 (6)	5 (4)
		Normal	12 (100)	10 (83)	12 (100)	34 (94)	115 (96)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	117 (98)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	118 (98)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	117 (98)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	111 (93)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	5 (4)
		Normal	11 (92)	0 (0)	0 (0)	11 (31)	90 (75)
Round Epithelial Cells [/HPF]	Day -30 to 0	Abnormal (not CS)	0 (0)	3 (25)	2 (17)	5 (14)	10 (8)
		Normal	4 (33)	4 (33)	3 (25)	11 (31)	33 (28)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 29 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Round Epithelial Cells [/HPF]	Day -30 to 0	Missing	0 (0)	0 (0)	0 (0)	0 (0)	6 (5)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	2 (6)	4 (3)
		Normal	2 (17)	3 (25)	3 (25)	8 (22)	24 (20)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	10 (8)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
		Normal	4 (33)	2 (17)	3 (25)	9 (25)	30 (25)
		Missing	0 (0)	2 (17)	1 (8)	3 (8)	9 (8)
	Day 8	Abnormal (not CS)	1 (8)	2 (17)	3 (25)	6 (17)	8 (7)
		Normal	3 (25)	3 (25)	2 (17)	8 (22)	27 (23)
		Missing	0 (0)	2 (17)	0 (0)	2 (6)	7 (6)
	Day 29	Abnormal (not CS)	2 (17)	2 (17)	2 (17)	6 (17)	7 (6)
		Normal	2 (17)	5 (42)	4 (33)	11 (31)	36 (30)
		Missing	1 (8)	0 (0)	0 (0)	1 (3)	5 (4)
	Day 50	Abnormal (not CS)	3 (25)	0 (0)	0 (0)	3 (8)	8 (7)
		Normal	2 (17)	0 (0)	0 (0)	2 (6)	21 (18)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 30 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Round Epithelial Cells [/HPF]	Day 50	Missing	1 (8)	0 (0)	0 (0)	1 (3)	7 (6)
Specific Gravity	Day -30 to 0	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	4 (3)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	116 (97)
	Day 1	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (6)	2 (2)
		Normal	11 (92)	11 (92)	12 (100)	34 (94)	118 (98)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)
	Day 8	Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	Day 29	Normal	12 (100)	12 (100)	12 (100)	36 (100)	117 (98)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	0 (0)	0 (0)	12 (33)	94 (78)
Urobilinogen [µmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 31 of 32)

Table 14.3.2-2.5.3-1: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b1

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Urobilinogen [µmol/L]	Day 2	Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	118 (98)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	116 (97)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	0 (0)	0 (0)	12 (33)	94 (78)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 32 of 32)

14.3.2-3 Vital signs

Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Diastolic Blood Pressure [mmHg]	Day -30 to 0		n	12	12	12	12	12	12	12	84
			Mean (SD)	80.0 (8.6)	79.1 (9.2)	79.3 (8.7)	70.9 (9.1)	81.0 (7.0)	78.3 (9.5)	73.9 (8.1)	77.5 (9.0)
			Min	67	64	67	56	72	62	61	56
			Median	80.0	79.0	80.0	71.0	81.0	79.0	73.0	77.5
			Max	98	90	94	84	97	94	93	98
	Day 1	Predose	n	12	12	12	12	12	12	12	84
			Mean (SD)	74.3 (8.4)	75.6 (10.0)	74.1 (11.5)	71.1 (7.0)	69.0 (8.3)	72.7 (13.4)	67.2 (7.8)	72.0 (9.8)
			Min	58	58	58	60	51	52	58	51
			Median	72.5	77.5	74.5	70.0	70.0	70.5	65.5	71.0
			Max	87	90	90	86	80	96	84	96
		1 hour	n	12	12	12	12	12	12	12	84
			Mean (SD)	67.9 (7.0)	70.5 (9.8)	67.3 (9.6)	61.8 (5.6)	63.1 (7.5)	67.4 (12.4)	64.8 (6.7)	66.1 (8.8)
			Min	55	56	55	55	53	47	56	47
			Median	69.0	70.5	66.5	61.5	61.5	66.5	63.0	65.0
			Max	78	88	89	72	81	87	76	89

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

Program: Tfsaf_VS_3_1.sas (Page 1 of 54)

Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Diastolic Blood Pressure [mmHg]	Day 1	3 hours	n	12	12	12	12	12	12	12	84
			Mean (SD)	71.4 (7.6)	68.9 (12.3)	68.8 (9.3)	65.9 (8.2)	64.2 (8.3)	67.3 (9.8)	63.1 (5.9)	67.1 (9.1)
			Min	59	54	52	51	55	52	55	51
			Median	70.5	66.5	70.0	69.5	63.5	65.0	62.5	66.5
			Max	84	94	80	73	86	83	75	94
		6 hours	n	12	12	12	12	12	12	12	84
			Mean (SD)	69.3 (8.5)	67.8 (7.2)	66.1 (8.6)	65.2 (8.6)	63.1 (9.1)	67.1 (9.3)	64.3 (8.4)	66.1 (8.5)
			Min	61	58	55	51	53	56	50	50
			Median	66.5	67.5	65.0	67.5	60.5	65.0	64.5	65.0
			Max	81	78	81	78	89	84	77	89
	Day 2		n	12	12	12	12	12	12	12	84
			Mean (SD)	71.9 (10.5)	72.3 (7.7)	72.0 (10.6)	68.6 (8.9)	71.5 (8.6)	71.8 (9.3)	68.1 (7.7)	70.9 (8.9)
			Min	52	60	56	57	57	56	61	52
			Median	70.5	73.5	74.0	69.5	69.5	70.5	66.5	70.0
			Max	91	85	86	85	83	84	86	91

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

Program: Tfsaf_VS_3_1.sas (Page 2 of 54)

Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Diastolic Blood Pressure [mmHg]	Day 8		n	12	11	12	12	12	12	12	83
			Mean (SD)	70.5 (6.3)	78.3 (9.5)	69.6 (11.8)	75.6 (6.3)	72.8 (7.5)	67.8 (10.4)	65.8 (6.1)	71.4 (9.2)
			Min	61	61	55	63	60	52	55	52
			Median	70.0	77.0	67.5	76.5	74.0	65.5	66.0	70.0
			Max	83	94	87	87	87	84	80	94
	Day 22	Predose	n	12	12	11	11	12	11	12	81
			Mean (SD)	70.7 (7.7)	79.0 (8.5)	72.0 (11.4)	74.0 (5.7)	72.5 (8.9)	71.9 (11.3)	66.8 (9.2)	72.4 (9.4)
			Min	57	60	53	67	55	56	54	53
			Median	71.0	79.0	74.0	74.0	73.0	70.0	67.5	73.0
			Max	82	91	86	84	85	90	83	91
		1 hour	n	12	12	11	11	12	11	0	69
			Mean (SD)	69.1 (7.8)	71.4 (6.9)	66.5 (8.0)	68.9 (7.9)	69.1 (6.9)	67.6 (10.2)	- (-)	68.8 (7.8)
			Min	57	59	55	60	57	46	-	46
			Median	68.0	70.0	67.0	69.0	70.5	69.0	-	69.0
			Max	83	87	78	82	78	84	-	87

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Diastolic Blood Pressure [mmHg]	Day 22	3 hours	n	12	12	11	11	12	11	0	69
			Mean (SD)	69.1 (9.2)	70.6 (7.9)	66.6 (9.3)	68.1 (7.7)	69.6 (7.7)	67.1 (11.0)	- (-)	68.6 (8.6)
			Min	55	59	53	57	56	49	-	49
			Median	65.0	70.0	68.0	67.0	71.0	69.0	-	69.0
			Max	84	83	82	81	81	85	-	85
		6 hours	n	12	12	11	11	12	11	0	69
			Mean (SD)	69.3 (7.3)	75.2 (8.5)	68.4 (9.4)	69.5 (8.6)	68.3 (9.1)	69.2 (13.1)	- (-)	70.0 (9.4)
			Min	60	62	54	56	58	45	-	45
			Median	70.5	73.5	68.0	70.0	68.5	72.0	-	71.0
			Max	80	88	86	81	85	90	-	90
	Day 29		n	12	12	11	11	12	11	12	81
			Mean (SD)	76.9 (6.8)	79.4 (9.2)	74.2 (10.3)	71.9 (9.3)	76.8 (6.7)	71.5 (10.2)	69.9 (8.7)	74.4 (9.1)
			Min	64	63	58	62	62	56	57	56
			Median	77.5	79.0	74.0	69.0	77.0	72.0	68.5	75.0
			Max	89	100	90	93	88	94	88	100

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Diastolic Blood Pressure [mmHg]	Day 43		n	12	12	11	10	12	11	12	80
			Mean (SD)	66.1 (8.1)	79.6 (8.1)	73.2 (10.0)	73.7 (7.2)	73.6 (8.0)	69.6 (10.4)	67.0 (9.0)	71.8 (9.5)
			Min	54	68	60	63	54	50	55	50
			Median	67.0	79.5	74.0	71.0	74.0	69.0	66.5	71.0
			Max	80	92	87	87	86	85	84	92
	Day 50		n	11	12	12	12	12	12	12	83
			Mean (SD)	71.4 (9.9)	78.3 (9.2)	70.6 (10.8)	76.3 (6.2)	68.8 (7.4)	75.8 (9.8)	63.4 (8.9)	72.1 (9.9)
			Min	55	65	55	66	56	63	51	51
			Median	72.0	77.5	77.0	76.5	71.0	75.0	62.5	73.0
			Max	87	90	81	86	80	91	79	91
	Day 85		n	12	12	11	10	11	11	12	79
			Mean (SD)	73.9 (10.7)	82.3 (7.3)	74.0 (10.7)	72.0 (8.8)	76.9 (6.2)	77.8 (10.9)	71.3 (9.3)	75.5 (9.6)
			Min	53	64	56	59	67	56	58	53
			Median	72.0	83.0	75.0	71.5	76.0	77.0	69.5	74.0
			Max	90	90	87	90	87	92	92	92

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Diastolic Blood Pressure [mmHg]	Day 184		n	0	0	5	0	0	0	0	5
			Mean (SD)	- (-)	- (-)	79.2 (13.7)	- (-)	- (-)	- (-)	- (-)	79.2 (13.7)
			Min	-	-	62	-	-	-	-	62
			Median	-	-	79.0	-	-	-	-	79.0
			Max	-	-	100	-	-	-	-	100
Pulse Rate [beats/min]	Day -30 to 0		n	12	12	12	12	12	12	12	84
			Mean (SD)	61.9 (6.6)	64.6 (9.4)	59.7 (6.7)	62.1 (7.0)	65.8 (8.6)	60.3 (7.6)	55.9 (6.4)	61.5 (7.9)
			Min	52	52	50	48	52	50	50	48
			Median	61.5	65.0	58.5	63.5	64.5	57.5	53.5	61.0
			Max	73	79	69	72	79	74	69	79
	Day 1	Predose	n	12	12	12	12	12	12	12	84
			Mean (SD)	59.0 (6.4)	66.2 (10.6)	59.5 (8.7)	59.4 (5.8)	63.3 (8.9)	64.8 (10.2)	59.6 (6.9)	61.7 (8.5)
			Min	52	52	50	51	49	42	51	42
			Median	56.5	62.5	56.0	58.5	63.0	65.0	59.5	61.0
			Max	70	90	80	68	81	81	71	90

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Pulse Rate [beats/min]	Day 1	1 hour	n	12	12	12	12	12	12	12	84
			Mean (SD)	68.3 (6.7)	67.2 (10.5)	64.1 (8.3)	62.5 (8.9)	63.6 (5.9)	66.7 (6.5)	63.3 (8.7)	65.1 (8.1)
			Min	59	55	51	51	55	51	50	50
			Median	68.0	65.0	63.5	61.5	64.0	68.5	64.0	65.0
			Max	80	89	75	80	73	73	78	89
		3 hours	n	12	12	12	12	12	12	12	84
			Mean (SD)	64.5 (3.8)	66.5 (8.0)	63.2 (7.9)	60.5 (8.4)	61.8 (6.8)	66.7 (9.2)	62.5 (8.0)	63.7 (7.7)
			Min	56	52	54	50	54	47	50	47
			Median	65.0	67.5	62.0	58.0	61.0	68.5	64.5	63.0
			Max	69	80	76	74	78	77	72	80
		6 hours	n	12	12	12	12	12	12	12	84
			Mean (SD)	67.8 (8.8)	70.4 (10.2)	65.6 (11.1)	64.1 (8.4)	65.0 (8.7)	69.1 (9.5)	65.8 (10.8)	66.8 (9.6)
			Min	51	56	52	52	50	52	50	50
			Median	68.0	68.0	65.0	61.5	65.0	69.5	65.0	67.0
			Max	82	97	89	81	80	80	85	97

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Pulse Rate [beats/min]	Day 2		n	12	12	12	12	12	12	12	84
			Mean (SD)	65.8 (8.5)	65.0 (6.8)	65.3 (9.2)	75.2 (10.3)	75.3 (12.8)	77.8 (9.5)	74.1 (9.6)	71.2 (10.7)
			Min	56	57	56	61	58	65	57	56
			Median	64.5	63.5	62.5	75.0	73.5	76.5	76.0	70.5
			Max	87	81	82	99	98	95	88	99
	Day 8		n	12	11	12	12	12	12	12	83
			Mean (SD)	62.7 (6.1)	65.5 (6.6)	58.1 (9.5)	60.8 (9.4)	62.3 (13.4)	62.9 (7.0)	59.0 (10.5)	61.6 (9.2)
			Min	50	56	49	50	47	51	46	46
			Median	64.0	65.0	53.5	59.0	60.5	62.5	57.0	61.0
			Max	71	77	77	80	100	75	87	100
	Day 22	Predose	n	12	12	11	11	12	11	12	81
			Mean (SD)	66.3 (9.4)	68.0 (9.9)	62.9 (14.9)	59.2 (7.8)	65.9 (13.1)	65.4 (9.9)	61.0 (6.3)	64.1 (10.5)
			Min	51	56	47	50	48	50	50	47
			Median	66.5	68.0	56.0	61.0	62.0	66.0	61.0	63.0
			Max	91	89	94	73	97	78	70	97

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Pulse Rate [beats/min]	Day 22	1 hour	n	12	12	11	11	12	11	0	69
			Mean (SD)	70.3 (8.1)	68.3 (7.6)	69.3 (13.3)	63.9 (8.7)	65.1 (6.1)	65.5 (9.1)	- (-)	67.1 (9.0)
			Min	59	59	48	52	58	50	-	48
			Median	69.0	68.0	76.0	64.0	64.5	67.0	-	66.0
			Max	85	86	86	79	79	78	-	86
		3 hours	n	12	12	11	11	12	11	0	69
			Mean (SD)	64.7 (5.6)	70.6 (8.7)	67.2 (15.0)	62.1 (8.5)	62.8 (8.3)	62.3 (10.2)	- (-)	65.0 (9.9)
			Min	55	59	45	50	52	47	-	45
			Median	67.5	67.0	71.0	60.0	61.5	59.0	-	66.0
			Max	71	85	89	83	80	74	-	89
		6 hours	n	12	12	11	11	12	11	0	69
			Mean (SD)	64.5 (5.6)	65.3 (8.9)	65.5 (12.9)	65.5 (8.4)	65.8 (8.8)	68.5 (7.8)	- (-)	65.8 (8.7)
			Min	57	55	45	55	51	56	-	45
			Median	63.5	64.5	68.0	65.0	63.5	71.0	-	65.0
			Max	75	84	86	85	81	79	-	86

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Pulse Rate [beats/min]	Day 29		n	12	12	11	11	12	11	12	81
			Mean (SD)	66.5 (9.4)	64.8 (8.5)	58.8 (13.2)	65.5 (9.0)	62.5 (10.2)	63.5 (9.9)	61.1 (9.0)	63.2 (9.9)
			Min	55	49	42	54	53	43	50	42
			Median	65.0	64.5	55.0	61.0	59.5	64.0	61.5	62.0
			Max	89	82	85	80	90	76	82	90
	Day 43		n	12	12	11	10	12	11	12	80
			Mean (SD)	67.4 (14.3)	64.8 (5.5)	61.4 (12.7)	64.0 (8.5)	67.1 (13.6)	64.0 (10.4)	61.4 (7.4)	64.3 (10.7)
			Min	51	55	50	51	55	47	51	47
			Median	63.0	65.5	57.0	64.5	61.0	62.0	59.5	62.0
			Max	105	74	86	75	96	86	76	105
	Day 50		n	11	12	12	12	12	12	12	83
			Mean (SD)	66.1 (8.7)	63.5 (8.6)	59.8 (10.4)	64.9 (8.0)	66.8 (10.7)	59.2 (7.6)	58.0 (6.8)	62.6 (9.1)
			Min	52	51	49	53	51	50	48	48
			Median	63.0	62.0	56.0	65.0	63.5	58.5	58.0	62.0
			Max	82	86	80	81	86	72	68	86

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Pulse Rate [beats/min]	Day 85		n	12	12	11	10	11	11	12	79
			Mean (SD)	68.1 (8.3)	67.2 (9.2)	61.5 (11.0)	66.9 (8.0)	62.8 (12.8)	61.7 (11.2)	61.0 (4.6)	64.2 (9.6)
			Min	57	55	48	58	49	43	54	43
			Median	67.5	65.5	64.0	65.5	59.0	60.0	61.5	64.0
			Max	81	91	82	81	98	80	67	98
	Day 184		n	0	0	5	0	0	0	0	5
			Mean (SD)	- (-)	- (-)	64.8 (9.7)	- (-)	- (-)	- (-)	- (-)	64.8 (9.7)
			Min	-	-	54	-	-	-	-	54
			Median	-	-	61.0	-	-	-	-	61.0
			Max	-	-	76	-	-	-	-	76
Respiratory Rate [breaths/min]	Day -30 to 0		n	12	12	12	12	12	12	12	84
			Mean (SD)	14.3 (2.2)	13.9 (2.5)	14.3 (2.0)	14.1 (2.6)	15.4 (3.0)	14.6 (2.2)	13.8 (2.1)	14.3 (2.4)
			Min	12	10	12	9	9	11	9	9
			Median	14.0	13.5	14.0	14.0	15.5	14.5	14.5	14.0
			Max	19	18	18	18	20	18	16	20

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Respiratory Rate [breaths/min]	Day 1	Predose	n	12	12	12	12	12	12	12	84
			Mean (SD)	12.1 (3.3)	12.1 (3.6)	11.7 (1.8)	12.8 (3.1)	13.6 (2.2)	13.9 (2.6)	13.1 (3.1)	12.7 (2.9)
			Min	9	8	8	8	11	10	8	8
			Median	10.5	11.0	12.0	12.5	13.5	14.0	14.0	12.0
			Max	18	20	14	18	17	18	17	20
		1 hour	n	12	12	12	12	12	12	12	84
			Mean (SD)	13.2 (3.0)	14.1 (3.2)	13.5 (2.2)	14.3 (2.5)	15.0 (1.6)	13.3 (2.0)	14.6 (2.4)	14.0 (2.5)
			Min	9	9	11	10	13	11	11	9
			Median	13.5	14.5	13.0	14.0	14.0	13.0	14.5	14.0
			Max	18	20	19	20	18	16	20	20
		3 hours	n	12	12	12	12	12	12	12	84
			Mean (SD)	13.3 (3.1)	13.8 (2.4)	12.7 (2.7)	14.1 (3.0)	14.8 (1.2)	13.3 (3.2)	13.0 (2.4)	13.5 (2.6)
			Min	9	11	9	11	13	9	10	9
			Median	13.5	13.5	12.5	13.0	14.0	14.0	12.5	14.0
			Max	18	19	20	20	17	20	18	20

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Respiratory Rate [breaths/min]	Day 1	6 hours	n	12	12	12	12	12	12	12	84
			Mean (SD)	15.6 (2.4)	13.5 (2.6)	14.3 (2.8)	13.8 (1.8)	16.1 (1.5)	15.6 (2.0)	15.3 (2.2)	14.9 (2.4)
			Min	11	8	11	11	14	12	10	8
			Median	15.5	13.5	14.0	13.5	16.0	16.0	16.0	15.0
			Max	20	17	19	16	18	19	18	20
	Day 2		n	12	12	12	12	12	12	12	84
			Mean (SD)	14.5 (3.1)	11.8 (2.7)	15.3 (3.7)	14.4 (3.2)	16.7 (3.3)	12.6 (3.6)	13.4 (4.6)	14.1 (3.7)
			Min	10	8	10	10	12	9	9	8
			Median	14.0	12.0	14.5	14.5	16.5	10.5	12.0	14.0
			Max	20	16	22	19	22	20	23	23
	Day 8		n	12	11	12	12	12	12	12	83
			Mean (SD)	13.2 (2.3)	14.7 (2.4)	14.5 (2.0)	13.4 (2.2)	13.8 (2.8)	14.7 (3.2)	15.1 (2.8)	14.2 (2.6)
			Min	10	12	11	11	9	10	12	9
			Median	13.5	16.0	15.0	13.0	14.0	15.0	15.0	14.0
			Max	18	18	17	17	18	20	20	20

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Respiratory Rate [breaths/min]	Day 22	Predose	n	12	12	11	11	12	11	12	81
			Mean (SD)	13.6 (2.5)	15.3 (2.2)	12.7 (2.6)	15.2 (2.4)	15.8 (2.1)	14.0 (1.6)	14.8 (2.7)	14.5 (2.5)
			Min	10	11	8	12	12	11	11	8
			Median	13.5	15.5	13.0	15.0	16.5	14.0	14.0	14.0
			Max	19	18	17	18	18	16	19	19
		1 hour	n	12	12	11	11	12	11	0	69
			Mean (SD)	14.0 (2.6)	16.3 (1.3)	14.8 (2.5)	15.5 (1.9)	15.2 (2.1)	14.6 (2.8)	- (-)	15.1 (2.3)
			Min	11	14	11	13	11	11	-	11
			Median	13.5	16.5	16.0	15.0	16.0	15.0	-	15.0
			Max	19	18	18	18	17	20	-	20
		3 hours	n	12	12	11	11	12	11	0	69
			Mean (SD)	12.3 (2.4)	14.9 (1.3)	13.5 (0.9)	15.4 (1.6)	14.6 (2.1)	15.7 (2.3)	- (-)	14.4 (2.2)
			Min	9	13	12	12	12	11	-	9
			Median	12.5	15.0	14.0	16.0	14.0	15.0	-	14.0
			Max	16	17	15	18	18	18	-	18

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Respiratory Rate [breaths/min]	Day 22	6 hours	n	12	12	11	11	12	11	0	69
			Mean (SD)	14.5 (1.8)	14.2 (2.9)	14.6 (2.2)	15.6 (2.3)	15.2 (1.1)	15.7 (2.2)	- (-)	15.0 (2.2)
			Min	10	9	11	11	13	10	-	9
			Median	14.5	14.0	15.0	16.0	15.0	16.0	-	15.0
			Max	17	19	18	18	17	18	-	19
	Day 29		n	12	12	11	11	12	11	12	81
			Mean (SD)	12.8 (2.6)	12.4 (1.8)	12.6 (1.6)	14.9 (1.9)	12.8 (2.7)	16.5 (3.2)	13.7 (3.4)	13.6 (2.8)
			Min	10	10	10	12	10	12	8	8
			Median	12.0	12.0	13.0	15.0	12.5	17.0	14.5	14.0
			Max	17	16	15	18	18	23	18	23
	Day 43		n	12	12	11	10	12	11	12	80
			Mean (SD)	16.8 (1.0)	13.8 (1.7)	13.9 (2.1)	13.6 (2.5)	14.3 (3.2)	17.3 (1.2)	13.3 (1.5)	14.7 (2.4)
			Min	16	12	11	11	10	15	11	10
			Median	16.0	13.5	14.0	13.0	14.5	18.0	13.0	15.0
			Max	18	17	17	20	18	19	16	20

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Respiratory Rate [breaths/min]	Day 50		n	11	12	12	12	12	12	12	83
			Mean (SD)	16.6 (1.9)	13.3 (3.7)	13.2 (3.1)	13.0 (3.0)	17.5 (1.8)	16.0 (2.9)	15.2 (2.9)	14.9 (3.2)
			Min	12	9	9	9	15	11	9	9
			Median	17.0	12.0	12.5	12.0	17.5	15.5	15.0	15.0
			Max	18	20	19	19	20	20	20	20
	Day 85		n	12	12	11	10	11	11	12	79
			Mean (SD)	15.3 (2.5)	13.4 (1.9)	13.7 (3.5)	14.3 (2.4)	15.5 (3.4)	16.2 (3.3)	16.1 (1.1)	14.9 (2.8)
			Min	10	10	10	12	10	11	14	10
			Median	15.5	13.5	12.0	13.5	16.0	17.0	16.0	15.0
			Max	18	17	20	19	20	20	18	20
	Day 184		n	0	0	5	0	0	0	0	5
			Mean (SD)	- (-)	- (-)	14.4 (3.2)	- (-)	- (-)	- (-)	- (-)	14.4 (3.2)
			Min	-	-	9	-	-	-	-	9
			Median	-	-	16.0	-	-	-	-	16.0
			Max	-	-	17	-	-	-	-	17

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Systolic Blood Pressure [mmHg]	Day -30 to 0		n	12	12	12	12	12	12	12	84
			Mean (SD)	122.7 (13.9)	119.8 (13.9)	124.3 (14.6)	116.3 (9.1)	129.3 (14.1)	116.4 (9.9)	118.4 (11.7)	121.0 (12.9)
			Min	101	98	104	102	110	98	97	97
			Median	121.0	117.5	123.5	117.0	130.0	116.5	117.0	119.0
			Max	142	142	155	136	150	134	140	155
	Day 1	Predose	n	12	12	12	12	12	12	12	84
			Mean (SD)	118.0 (14.0)	120.7 (16.7)	118.7 (10.5)	120.3 (10.5)	119.1 (10.2)	117.2 (13.1)	114.5 (11.1)	118.3 (12.2)
			Min	95	96	103	100	104	92	94	92
			Median	115.5	123.0	120.5	120.5	119.0	115.0	114.0	117.0
			Max	149	148	136	135	137	142	134	149
		1 hour	n	12	12	12	12	12	12	12	84
			Mean (SD)	119.3 (10.2)	115.9 (12.8)	115.9 (9.5)	114.2 (8.9)	115.7 (13.7)	116.6 (15.4)	115.9 (9.2)	116.2 (11.3)
			Min	105	98	104	99	89	90	98	89
			Median	120.0	113.0	115.5	112.0	114.0	115.5	117.0	116.0
			Max	139	138	132	127	139	143	126	143

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Systolic Blood Pressure [mmHg]	Day 1	3 hours	n	12	12	12	12	12	12	12	84
			Mean (SD)	118.1 (9.8)	114.9 (14.4)	117.9 (11.9)	110.2 (8.6)	116.0 (10.8)	114.4 (9.8)	115.1 (10.6)	115.2 (10.8)
			Min	106	96	101	86	102	93	101	86
			Median	116.5	117.0	121.5	113.5	115.5	116.0	118.5	115.5
			Max	139	139	138	117	137	131	130	139
		6 hours	n	12	12	12	12	12	12	12	84
			Mean (SD)	118.2 (8.4)	112.5 (10.4)	116.5 (11.5)	112.8 (7.5)	114.8 (12.7)	113.6 (9.7)	117.3 (12.3)	115.1 (10.3)
			Min	102	99	99	92	100	98	96	92
			Median	118.0	113.5	115.5	113.5	112.5	112.0	120.5	114.5
			Max	128	133	136	121	142	130	134	142
	Day 2		n	12	12	12	12	12	12	12	84
			Mean (SD)	115.8 (7.5)	116.8 (12.1)	119.6 (13.5)	119.1 (8.0)	122.7 (9.3)	118.8 (13.0)	118.3 (11.1)	118.7 (10.7)
			Min	106	96	100	106	108	91	101	91
			Median	117.0	115.5	124.0	120.0	123.0	119.5	119.5	119.0
			Max	129	140	138	131	138	137	132	140

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Systolic Blood Pressure [mmHg]	Day 8		n	12	11	12	12	12	12	12	83
			Mean (SD)	115.6 (10.8)	116.2 (12.1)	121.9 (14.1)	117.9 (9.7)	122.5 (10.3)	114.8 (8.8)	113.2 (11.1)	117.5 (11.2)
			Min	98	99	99	100	103	97	92	92
			Median	118.0	117.0	121.5	119.5	121.5	113.5	113.5	118.0
			Max	132	138	141	134	138	127	127	141
	Day 22	Predose	n	12	12	11	11	12	11	12	81
			Mean (SD)	118.0 (11.5)	117.9 (12.2)	118.9 (12.2)	118.6 (13.6)	122.8 (10.1)	115.9 (13.7)	116.9 (14.9)	118.5 (12.3)
			Min	102	96	100	96	105	102	98	96
			Median	120.0	119.0	124.0	118.0	122.5	109.0	114.5	119.0
			Max	132	133	135	143	136	140	140	143
		1 hour	n	12	12	11	11	12	11	0	69
			Mean (SD)	117.3 (12.1)	114.8 (10.8)	114.0 (10.3)	117.5 (15.2)	122.3 (8.9)	112.8 (14.2)	- (-)	116.5 (12.0)
			Min	97	95	101	91	104	78	-	78
			Median	119.5	115.0	112.0	125.0	121.5	115.0	-	116.0
			Max	134	134	131	139	137	129	-	139

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Systolic Blood Pressure [mmHg]	Day 22	3 hours	n	12	12	11	11	12	11	0	69
			Mean (SD)	116.7 (11.9)	113.7 (9.9)	117.0 (15.6)	111.6 (11.4)	121.7 (8.6)	112.8 (13.9)	- (-)	115.7 (12.0)
			Min	99	99	101	87	111	81	-	81
			Median	119.5	113.0	111.0	112.0	120.0	115.0	-	115.0
			Max	132	129	147	127	137	133	-	147
		6 hours	n	12	12	11	11	12	11	0	69
			Mean (SD)	114.8 (9.1)	115.2 (9.1)	116.1 (14.1)	114.5 (11.1)	118.2 (7.9)	115.9 (18.2)	- (-)	115.8 (11.6)
			Min	99	98	99	87	102	80	-	80
			Median	116.5	118.0	114.0	115.0	120.0	121.0	-	117.0
			Max	127	125	145	130	128	147	-	147
	Day 29		n	12	12	11	11	12	11	12	81
			Mean (SD)	120.8 (9.8)	117.6 (12.6)	119.3 (16.6)	112.3 (13.3)	123.3 (8.9)	113.4 (14.8)	115.0 (12.0)	117.5 (12.8)
			Min	101	96	100	90	110	95	96	90
			Median	121.5	119.0	115.0	111.0	122.5	108.0	116.5	117.0
			Max	139	140	153	142	139	148	137	153

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Systolic Blood Pressure [mmHg]	Day 43		n	12	12	11	10	12	11	12	80
			Mean (SD)	117.3 (11.5)	121.2 (15.1)	121.3 (13.6)	118.6 (10.9)	125.7 (8.8)	111.7 (13.3)	112.8 (9.4)	118.4 (12.4)
			Min	99	98	103	100	115	94	100	94
			Median	118.5	122.0	118.0	118.5	123.5	114.0	112.0	118.0
			Max	135	142	139	134	147	133	130	147
	Day 50		n	11	12	12	12	12	12	12	83
			Mean (SD)	115.1 (11.9)	119.8 (13.9)	119.6 (12.2)	123.5 (12.1)	119.6 (7.6)	113.9 (13.3)	111.7 (11.2)	117.6 (12.1)
			Min	102	94	102	107	109	87	94	87
			Median	114.0	122.0	123.5	120.5	119.0	115.0	111.0	118.0
			Max	137	140	140	143	130	132	131	143
	Day 85		n	12	12	11	10	11	11	12	79
			Mean (SD)	116.5 (10.7)	125.0 (10.8)	120.3 (12.8)	118.4 (12.2)	120.1 (7.1)	113.5 (15.9)	115.1 (10.3)	118.4 (11.8)
			Min	98	99	104	98	107	88	102	88
			Median	118.0	123.5	116.0	116.0	122.0	110.0	114.0	119.0
			Max	132	138	136	140	128	140	136	140

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Systolic Blood Pressure [mmHg]	Day 184		n	0	0	5	0	0	0	0	5
			Mean (SD)	- (-)	- (-)	124.4 (19.5)	- (-)	- (-)	- (-)	- (-)	124.4 (19.5)
			Min	-	-	101	-	-	-	-	101
			Median	-	-	120.0	-	-	-	-	120.0
			Max	-	-	151	-	-	-	-	151
Temperature [°C]	Day -30 to 0		n	12	12	12	12	12	12	12	84
			Mean (SD)	36.23 (0.21)	36.29 (0.29)	36.28 (0.33)	36.34 (0.33)	36.36 (0.34)	36.21 (0.29)	36.23 (0.27)	36.28 (0.29)
			Min	35.9	36.0	36.0	36.0	36.0	36.0	36.0	35.9
			Median	36.25	36.15	36.20	36.30	36.25	36.10	36.10	36.20
			Max	36.6	36.9	36.9	37.0	37.0	36.9	36.8	37.0
	Day 1	Predose	n	12	12	12	12	12	12	12	84
			Mean (SD)	36.37 (0.26)	36.27 (0.28)	36.43 (0.23)	36.15 (0.18)	36.32 (0.27)	36.21 (0.27)	36.25 (0.28)	36.28 (0.26)
			Min	36.0	35.9	36.0	35.7	36.0	35.8	35.7	35.7
			Median	36.35	36.25	36.50	36.10	36.30	36.30	36.30	36.30
			Max	37.0	36.9	36.8	36.4	36.9	36.6	36.6	37.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Temperature [°C]	Day 1	1 hour	n	12	12	12	12	12	12	12	84
			Mean (SD)	36.30 (0.32)	36.11 (0.31)	36.39 (0.34)	36.10 (0.22)	36.29 (0.24)	36.30 (0.32)	36.15 (0.23)	36.23 (0.30)
			Min	35.7	35.6	35.6	35.9	36.0	35.8	35.7	35.6
			Median	36.35	36.10	36.40	36.05	36.30	36.30	36.15	36.30
			Max	37.0	36.5	36.9	36.5	36.9	36.8	36.5	37.0
		3 hours	n	12	12	12	12	12	12	12	84
			Mean (SD)	36.34 (0.39)	36.16 (0.32)	36.45 (0.28)	36.26 (0.37)	36.29 (0.36)	36.37 (0.30)	36.28 (0.25)	36.31 (0.33)
			Min	35.6	35.7	35.9	35.7	35.8	35.9	35.7	35.6
			Median	36.40	36.20	36.50	36.30	36.30	36.50	36.30	36.30
			Max	37.0	36.6	36.8	36.7	37.0	36.8	36.7	37.0
		6 hours	n	12	12	12	12	12	12	12	84
			Mean (SD)	36.33 (0.43)	36.23 (0.40)	36.48 (0.33)	36.35 (0.27)	36.33 (0.34)	36.27 (0.36)	36.37 (0.44)	36.33 (0.37)
			Min	35.7	35.5	36.0	36.0	35.7	35.7	35.7	35.5
			Median	36.40	36.20	36.45	36.30	36.30	36.30	36.40	36.30
			Max	37.0	36.9	36.9	36.9	37.1	36.9	36.9	37.1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Temperature [°C]	Day 2		n	12	12	12	12	12	12	12	84
			Mean (SD)	36.24 (0.33)	36.39 (0.24)	36.59 (0.48)	36.66 (0.38)	36.78 (0.47)	36.96 (0.54)	37.39 (0.41)	36.72 (0.54)
			Min	35.7	36.1	35.9	36.1	36.0	36.1	36.4	35.7
			Median	36.30	36.40	36.50	36.85	36.80	36.90	37.35	36.60
			Max	36.8	36.9	37.7	37.2	37.6	38.0	37.9	38.0
	Day 8		n	12	11	12	12	12	12	12	83
			Mean (SD)	36.36 (0.23)	36.17 (0.28)	36.28 (0.31)	36.06 (0.13)	36.27 (0.36)	36.21 (0.27)	36.08 (0.39)	36.20 (0.30)
			Min	36.0	35.9	35.8	35.9	35.8	35.6	35.5	35.5
			Median	36.40	36.00	36.30	36.05	36.15	36.25	36.10	36.10
			Max	36.8	36.6	36.8	36.3	36.9	36.6	36.9	36.9
	Day 22	Predose	n	12	12	11	11	12	11	12	81
			Mean (SD)	36.27 (0.29)	36.16 (0.22)	36.33 (0.26)	35.92 (0.30)	36.26 (0.34)	36.07 (0.30)	36.18 (0.25)	36.17 (0.30)
			Min	35.9	35.9	35.9	35.6	36.0	35.7	35.7	35.6
			Median	36.10	36.20	36.40	35.90	36.00	36.00	36.10	36.10
			Max	36.7	36.5	36.6	36.4	37.0	36.7	36.5	37.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Temperature [°C]	Day 22	1 hour	n	12	12	11	11	12	11	0	69
			Mean (SD)	36.19 (0.26)	36.09 (0.25)	36.33 (0.46)	36.29 (0.16)	36.33 (0.35)	36.14 (0.26)	- (-)	36.23 (0.31)
			Min	35.9	35.7	35.7	36.1	35.9	35.8	-	35.7
			Median	36.10	36.05	36.20	36.30	36.20	36.20	-	36.20
			Max	36.8	36.6	37.2	36.6	36.9	36.5	-	37.2
		3 hours	n	12	12	11	11	12	11	0	69
			Mean (SD)	36.23 (0.25)	36.31 (0.25)	36.27 (0.30)	36.11 (0.40)	36.19 (0.21)	36.25 (0.38)	- (-)	36.23 (0.30)
			Min	35.9	35.8	35.8	35.6	35.9	35.7	-	35.6
			Median	36.30	36.30	36.20	36.20	36.10	36.30	-	36.30
			Max	36.6	36.7	36.9	36.6	36.5	36.8	-	36.9
		6 hours	n	12	12	11	11	12	11	0	69
			Mean (SD)	36.33 (0.24)	36.17 (0.31)	36.47 (0.30)	36.54 (0.34)	36.34 (0.32)	36.38 (0.39)	- (-)	36.37 (0.33)
			Min	36.1	35.7	36.1	35.9	35.9	35.6	-	35.6
			Median	36.30	36.10	36.40	36.50	36.30	36.30	-	36.30
			Max	36.9	36.6	36.9	37.3	36.9	36.9	-	37.3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Temperature [°C]	Day 29		n	12	12	11	11	12	11	12	81
			Mean (SD)	36.28 (0.20)	36.22 (0.38)	36.30 (0.28)	36.47 (0.23)	36.17 (0.21)	36.16 (0.21)	36.18 (0.26)	36.25 (0.27)
			Min	36.0	35.5	35.9	36.1	35.8	35.9	35.8	35.5
			Median	36.25	36.20	36.40	36.50	36.15	36.10	36.20	36.20
			Max	36.6	36.9	36.8	36.8	36.5	36.5	36.6	36.9
	Day 43		n	12	12	11	10	12	11	12	80
			Mean (SD)	36.33 (0.34)	36.19 (0.51)	36.25 (0.42)	36.35 (0.34)	36.23 (0.32)	36.18 (0.37)	36.16 (0.35)	36.24 (0.38)
			Min	35.7	35.5	35.5	36.0	35.7	35.7	35.6	35.5
			Median	36.35	36.10	36.10	36.30	36.20	36.10	36.15	36.20
			Max	36.8	37.2	37.0	36.8	37.0	36.9	37.0	37.2
	Day 50		n	11	12	12	12	12	12	12	83
			Mean (SD)	36.21 (0.33)	35.97 (0.26)	36.19 (0.31)	36.18 (0.28)	36.29 (0.45)	36.04 (0.28)	36.18 (0.25)	36.15 (0.32)
			Min	35.7	35.5	35.9	35.5	35.5	35.5	35.7	35.5
			Median	36.30	36.00	36.10	36.20	36.20	36.10	36.15	36.10
			Max	36.8	36.5	36.7	36.5	37.1	36.5	36.5	37.1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	50 µg (N=12)	60 µg (N=12)	Total (N=84)
Temperature [°C]	Day 85		n	12	12	11	10	11	11	12	79
			Mean (SD)	36.39 (0.31)	36.36 (0.25)	36.27 (0.30)	36.41 (0.28)	36.17 (0.21)	36.42 (0.33)	36.41 (0.34)	36.35 (0.29)
			Min	35.8	36.0	35.9	36.0	35.9	35.9	35.9	35.8
			Median	36.40	36.35	36.30	36.50	36.10	36.50	36.50	36.30
			Max	36.9	36.8	36.8	36.9	36.6	36.9	36.9	36.9
	Day 184		n	0	0	5	0	0	0	0	5
			Mean (SD)	- (-)	- (-)	36.18 (0.41)	- (-)	- (-)	- (-)	- (-)	36.18 (0.41)
			Min	-	-	35.7	-	-	-	-	35.7
			Median	-	-	36.10	-	-	-	-	36.10
			Max	-	-	36.6	-	-	-	-	36.6

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Diastolic Blood Pressure [mmHg]	Day -30 to 0		n	12	12	12	36	120
			Mean (SD)	77.7 (4.6)	72.9 (4.9)	84.5 (7.8)	78.4 (7.5)	77.8 (8.5)
			Min	71	63	75	63	56
			Median	76.5	73.5	84.5	77.0	77.0
			Max	88	81	101	101	101
	Day 1	Predose	n	12	12	12	36	120
			Mean (SD)	82.2 (6.9)	68.8 (6.5)	82.9 (10.8)	78.0 (10.4)	73.8 (10.3)
			Min	70	57	66	57	51
			Median	84.0	68.5	82.5	76.0	73.0
			Max	90	79	105	105	105
		1 hour	n	12	12	12	36	120
			Mean (SD)	73.5 (8.9)	72.3 (6.7)	74.8 (9.8)	73.5 (8.4)	68.3 (9.3)
			Min	53	62	62	53	47
			Median	72.5	73.0	75.5	72.5	68.0
			Max	86	84	92	92	92

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Diastolic Blood Pressure [mmHg]	Day 1	3 hours	n	12	12	12	36	120
			Mean (SD)	75.5 (7.2)	66.1 (6.8)	75.8 (7.9)	72.4 (8.4)	68.7 (9.2)
			Min	64	54	62	54	51
			Median	78.0	67.5	76.5	72.5	68.0
			Max	85	75	89	89	94
		6 hours	n	12	12	12	36	120
			Mean (SD)	75.9 (6.9)	65.9 (4.6)	74.9 (5.5)	72.3 (7.2)	67.9 (8.6)
			Min	69	60	60	60	50
			Median	73.0	65.5	77.0	71.5	67.0
			Max	86	75	80	86	89
	Day 2		n	12	12	12	36	120
			Mean (SD)	79.8 (7.2)	69.3 (7.2)	80.4 (9.0)	76.5 (9.2)	72.6 (9.3)
			Min	72	56	66	56	52
			Median	78.0	69.5	81.0	75.0	72.0
			Max	95	81	97	97	97

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Diastolic Blood Pressure [mmHg]	Day 8		n	12	12	12	36	119
			Mean (SD)	79.3 (7.4)	72.3 (6.3)	80.7 (9.7)	77.4 (8.5)	73.2 (9.4)
			Min	68	60	68	60	52
			Median	79.0	73.0	79.5	75.0	73.0
			Max	93	85	99	99	99
	Day 22	Predose	n	12	12	12	36	117
			Mean (SD)	82.3 (7.4)	68.3 (7.3)	82.9 (7.2)	77.8 (9.9)	74.1 (9.8)
			Min	68	51	75	51	51
			Median	83.5	69.5	80.0	79.0	75.0
			Max	91	79	100	100	100
		1 hour	n	12	11	12	35	104
			Mean (SD)	73.3 (5.7)	68.3 (7.8)	74.3 (7.4)	72.1 (7.3)	69.9 (7.8)
			Min	64	55	62	55	46
			Median	73.5	69.0	75.0	72.0	70.0
			Max	84	79	84	84	87

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Diastolic Blood Pressure [mmHg]	Day 22	3 hours	n	12	11	12	35	104
			Mean (SD)	76.1 (7.7)	64.5 (4.5)	77.6 (6.4)	72.9 (8.5)	70.0 (8.8)
			Min	66	59	68	59	49
			Median	75.0	64.0	77.5	73.0	69.0
			Max	92	73	91	92	92
		6 hours	n	12	11	12	35	104
			Mean (SD)	74.5 (12.7)	65.5 (4.7)	78.0 (11.5)	72.9 (11.3)	71.0 (10.1)
			Min	56	58	59	56	45
			Median	72.0	67.0	79.0	70.0	70.5
			Max	95	72	99	99	99
	Day 29		n	12	12	11	35	116
			Mean (SD)	81.6 (5.1)	69.3 (4.7)	81.0 (5.5)	77.2 (7.6)	75.3 (8.7)
			Min	74	61	71	61	56
			Median	80.5	69.0	84.0	77.0	76.0
			Max	91	77	86	91	100

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Diastolic Blood Pressure [mmHg]	Day 43		n	11	12	0	23	103
			Mean (SD)	82.5 (8.7)	71.1 (7.9)	- (-)	76.6 (10.0)	72.9 (9.8)
			Min	71	60	-	60	50
			Median	80.0	71.0	-	78.0	72.0
			Max	101	86	-	101	101
	Day 50		n	12	0	0	12	95
			Mean (SD)	81.8 (7.1)	- (-)	- (-)	81.8 (7.1)	73.3 (10.1)
			Min	73	-	-	73	51
			Median	79.5	-	-	79.5	74.0
			Max	94	-	-	94	94
	Day 85		n	0	0	0	0	79
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	75.5 (9.6)
			Min	-	-	-	-	53
			Median	-	-	-	-	74.0
			Max	-	-	-	-	92

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Diastolic Blood Pressure [mmHg]	Day 184		n	0	0	0	0	5
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	79.2 (13.7)
			Min	-	-	-	-	62
			Median	-	-	-	-	79.0
			Max	-	-	-	-	100
Pulse Rate [beats/min]	Day -30 to 0		n	12	12	12	36	120
			Mean (SD)	63.0 (8.3)	70.3 (9.1)	66.9 (10.0)	66.7 (9.4)	63.0 (8.6)
			Min	51	56	55	51	48
			Median	61.5	68.5	62.5	65.0	62.0
			Max	79	83	86	86	86
	Day 1	Predose	n	12	12	12	36	120
			Mean (SD)	64.6 (9.3)	67.8 (11.8)	63.6 (8.8)	65.3 (9.9)	62.8 (9.1)
			Min	53	53	52	52	42
			Median	63.0	63.0	60.0	61.5	61.5
			Max	80	90	79	90	90

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Pulse Rate [beats/min]	Day 1	1 hour	n	12	12	12	36	120
			Mean (SD)	66.0 (11.7)	59.1 (6.6)	67.1 (11.4)	64.1 (10.5)	64.8 (8.8)
			Min	47	49	52	47	47
			Median	66.0	57.5	62.5	62.5	64.0
			Max	83	69	86	86	89
		3 hours	n	12	12	12	36	120
			Mean (SD)	62.9 (9.1)	65.0 (7.6)	63.6 (10.6)	63.8 (9.0)	63.7 (8.0)
			Min	48	53	52	48	47
			Median	63.0	65.5	59.5	64.0	63.5
			Max	80	78	81	81	81
		6 hours	n	12	12	12	36	120
			Mean (SD)	62.3 (8.9)	67.2 (6.8)	64.9 (8.4)	64.8 (8.1)	66.2 (9.2)
			Min	50	53	51	50	50
			Median	62.0	67.0	64.5	64.5	65.5
			Max	81	77	77	81	97

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Pulse Rate [beats/min]	Day 2		n	12	12	12	36	120
			Mean (SD)	68.1 (11.4)	75.8 (9.4)	71.7 (11.9)	71.9 (11.1)	71.4 (10.8)
			Min	50	64	54	50	50
			Median	65.5	73.0	70.5	70.5	70.5
			Max	84	90	93	93	99
	Day 8		n	12	12	12	36	119
			Mean (SD)	62.4 (9.3)	65.9 (8.1)	59.5 (12.6)	62.6 (10.2)	61.9 (9.5)
			Min	48	54	45	45	45
			Median	61.5	64.5	54.0	60.5	61.0
			Max	80	77	91	91	100
	Day 22	Predose	n	12	12	12	36	117
			Mean (SD)	64.9 (8.7)	69.0 (7.7)	64.8 (9.2)	66.2 (8.5)	64.8 (10.0)
			Min	53	59	55	53	47
			Median	63.0	67.0	64.0	65.0	63.0
			Max	78	84	87	87	97

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Pulse Rate [beats/min]	Day 22	1 hour	n	12	11	12	35	104
			Mean (SD)	65.5 (10.1)	58.7 (6.0)	67.3 (10.0)	64.0 (9.5)	66.0 (9.2)
			Min	50	50	53	50	48
			Median	67.0	59.0	62.5	62.0	65.0
			Max	81	73	86	86	86
		3 hours	n	12	11	12	35	104
			Mean (SD)	61.0 (9.1)	68.5 (8.8)	60.1 (7.9)	63.1 (9.2)	64.3 (9.6)
			Min	45	59	49	45	45
			Median	60.0	67.0	59.5	62.0	64.0
			Max	77	89	80	89	89
		6 hours	n	12	11	12	35	104
			Mean (SD)	62.3 (8.0)	67.8 (8.0)	64.4 (9.2)	64.8 (8.5)	65.5 (8.6)
			Min	49	54	55	49	45
			Median	62.5	69.0	63.0	64.0	64.5
			Max	76	83	86	86	86

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Pulse Rate [beats/min]	Day 29		n	12	12	11	35	116
			Mean (SD)	64.3 (6.9)	67.6 (7.2)	57.4 (10.5)	63.3 (9.1)	63.3 (9.6)
			Min	52	57	42	42	42
			Median	63.0	69.0	55.0	63.0	62.0
			Max	76	76	80	80	90
	Day 43		n	9	12	0	21	101
			Mean (SD)	61.6 (9.6)	66.0 (5.7)	- (-)	64.1 (7.7)	64.3 (10.1)
			Min	48	56	-	48	47
			Median	59.0	67.5	-	66.0	63.0
			Max	80	74	-	80	105
	Day 50		n	12	0	0	12	95
			Mean (SD)	64.8 (9.4)	- (-)	- (-)	64.8 (9.4)	62.8 (9.1)
			Min	48	-	-	48	48
			Median	64.5	-	-	64.5	62.0
			Max	83	-	-	83	86

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Pulse Rate [beats/min]	Day 85		n	0	0	0	0	79
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	64.2 (9.6)
			Min	-	-	-	-	43
			Median	-	-	-	-	64.0
			Max	-	-	-	-	98
	Day 184		n	0	0	0	0	5
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	64.8 (9.7)
			Min	-	-	-	-	54
			Median	-	-	-	-	61.0
			Max	-	-	-	-	76
Respiratory Rate [breaths/min]	Day -30 to 0		n	12	12	12	36	120
			Mean (SD)	13.4 (3.3)	13.3 (3.1)	12.2 (1.7)	12.9 (2.8)	13.9 (2.6)
			Min	8	8	10	8	8
			Median	13.5	13.0	12.0	13.0	14.0
			Max	20	17	16	20	20

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Respiratory Rate [breaths/min]	Day 1	Predose	n	12	12	12	36	120
			Mean (SD)	13.4 (1.9)	12.8 (3.1)	15.7 (1.0)	13.9 (2.5)	13.1 (2.8)
			Min	10	8	14	8	8
			Median	13.0	12.5	15.5	14.0	13.0
			Max	17	20	17	20	20
		1 hour	n	12	12	12	36	120
			Mean (SD)	12.8 (1.6)	14.2 (3.4)	15.4 (1.2)	14.1 (2.4)	14.0 (2.5)
			Min	10	10	14	10	9
			Median	13.0	15.0	15.5	14.5	14.0
			Max	15	20	18	20	20
		3 hours	n	12	12	12	36	120
			Mean (SD)	12.7 (1.4)	14.1 (1.6)	14.8 (1.3)	13.9 (1.6)	13.6 (2.4)
			Min	11	11	12	11	9
			Median	12.5	15.0	15.0	14.0	14.0
			Max	15	15	17	17	20

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Respiratory Rate [breaths/min]	Day 1	6 hours	n	12	12	12	36	120
			Mean (SD)	13.9 (2.5)	14.6 (2.6)	14.8 (3.1)	14.4 (2.7)	14.8 (2.5)
			Min	10	9	8	8	8
			Median	14.0	15.0	15.5	15.0	15.0
			Max	18	19	18	19	20
	Day 2		n	12	12	12	36	120
			Mean (SD)	13.1 (2.4)	14.3 (3.1)	15.2 (1.9)	14.2 (2.6)	14.1 (3.4)
			Min	10	9	11	9	8
			Median	12.5	15.5	16.0	15.0	14.0
			Max	17	19	17	19	23
	Day 8		n	12	12	12	36	119
			Mean (SD)	15.2 (1.6)	14.0 (3.5)	14.3 (2.3)	14.5 (2.5)	14.3 (2.6)
			Min	12	9	11	9	9
			Median	15.5	13.0	15.0	15.0	14.0
			Max	18	20	18	20	20

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Respiratory Rate [breaths/min]	Day 22	Predose	n	12	12	12	36	117
			Mean (SD)	12.2 (2.2)	14.1 (3.9)	13.2 (1.3)	13.1 (2.8)	14.1 (2.6)
			Min	10	7	11	7	7
			Median	11.5	14.0	13.5	12.5	14.0
			Max	18	20	15	20	20
		1 hour	n	12	11	12	35	104
			Mean (SD)	13.4 (2.0)	14.5 (3.6)	12.4 (1.0)	13.4 (2.5)	14.5 (2.5)
			Min	11	8	11	8	8
			Median	13.0	13.0	12.0	13.0	14.0
			Max	17	19	14	19	20
		3 hours	n	12	11	12	35	104
			Mean (SD)	12.5 (2.3)	13.7 (3.2)	12.8 (1.1)	13.0 (2.3)	13.9 (2.3)
			Min	9	9	11	9	9
			Median	12.5	13.0	12.5	13.0	14.0
			Max	16	18	14	18	18

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Respiratory Rate [breaths/min]	Day 22	6 hours	n	12	11	12	35	104
			Mean (SD)	12.9 (3.3)	14.3 (3.2)	14.8 (1.9)	14.0 (2.9)	14.6 (2.5)
			Min	9	9	12	9	9
			Median	12.0	15.0	15.0	14.0	15.0
			Max	19	20	18	20	20
	Day 29		n	12	12	11	35	116
			Mean (SD)	12.9 (1.8)	11.8 (3.5)	14.5 (1.9)	13.0 (2.7)	13.4 (2.8)
			Min	11	6	11	6	6
			Median	13.0	11.0	15.0	13.0	13.0
			Max	17	18	17	18	23
	Day 43		n	11	12	0	23	103
			Mean (SD)	12.8 (2.5)	13.9 (3.2)	- (-)	13.4 (2.9)	14.4 (2.6)
			Min	10	7	-	7	7
			Median	12.0	13.5	-	13.0	14.0
			Max	19	19	-	19	20

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Respiratory Rate [breaths/min]	Day 50		n	12	0	0	12	95
			Mean (SD)	13.8 (1.9)	- (-)	- (-)	13.8 (1.9)	14.8 (3.1)
			Min	11	-	-	11	9
			Median	14.0	-	-	14.0	15.0
			Max	17	-	-	17	20
	Day 85		n	0	0	0	0	79
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	14.9 (2.8)
			Min	-	-	-	-	10
			Median	-	-	-	-	15.0
			Max	-	-	-	-	20
	Day 184		n	0	0	0	0	5
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	14.4 (3.2)
			Min	-	-	-	-	9
			Median	-	-	-	-	16.0
			Max	-	-	-	-	17

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Systolic Blood Pressure [mmHg]	Day -30 to 0		n	12	12	12	36	120
			Mean (SD)	124.7 (9.8)	126.5 (11.8)	134.3 (14.2)	128.5 (12.5)	123.3 (13.2)
			Min	112	107	111	107	97
			Median	126.5	124.5	139.0	129.0	121.0
			Max	140	145	157	157	157
	Day 1	Predose	n	12	12	12	36	120
			Mean (SD)	124.2 (8.5)	123.3 (12.4)	132.7 (13.6)	126.7 (12.1)	120.9 (12.7)
			Min	111	106	116	106	92
			Median	125.0	123.5	127.5	125.0	121.0
			Max	140	143	161	161	161
		1 hour	n	12	12	12	36	120
			Mean (SD)	116.8 (12.0)	124.3 (12.7)	119.9 (13.5)	120.3 (12.7)	117.4 (11.8)
			Min	88	104	102	88	88
			Median	120.0	120.5	121.0	120.0	117.5
			Max	134	142	144	144	144

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Systolic Blood Pressure [mmHg]	Day 1	3 hours	n	12	12	12	36	120
			Mean (SD)	116.8 (12.5)	119.8 (14.0)	120.2 (13.1)	118.9 (12.9)	116.3 (11.6)
			Min	94	98	99	94	86
			Median	117.5	118.0	120.0	118.5	116.0
			Max	141	146	149	149	149
		6 hours	n	12	12	12	36	120
			Mean (SD)	118.6 (10.6)	118.8 (11.3)	123.3 (10.6)	120.2 (10.8)	116.6 (10.7)
			Min	100	102	108	100	92
			Median	119.0	121.0	120.5	120.5	116.5
			Max	138	138	148	148	148
	Day 2		n	12	12	12	36	120
			Mean (SD)	125.8 (10.5)	120.2 (12.4)	128.7 (13.5)	124.9 (12.4)	120.6 (11.5)
			Min	108	102	102	102	91
			Median	128.5	117.5	128.0	128.0	120.0
			Max	142	140	152	152	152

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Systolic Blood Pressure [mmHg]	Day 8		n	12	12	12	36	119
			Mean (SD)	128.9 (16.3)	126.1 (12.3)	131.0 (18.1)	128.7 (15.5)	120.8 (13.6)
			Min	114	105	103	103	92
			Median	125.0	128.0	129.5	126.0	120.0
			Max	172	148	169	172	172
	Day 22	Predose	n	12	12	12	36	117
			Mean (SD)	125.3 (11.4)	121.2 (9.2)	136.0 (17.7)	127.5 (14.4)	121.2 (13.6)
			Min	106	110	114	106	96
			Median	125.0	119.0	130.5	124.5	121.0
			Max	141	140	167	167	167
		1 hour	n	12	11	12	35	104
			Mean (SD)	117.8 (8.6)	120.5 (9.1)	122.2 (16.0)	120.2 (11.6)	117.7 (11.9)
			Min	104	106	98	98	78
			Median	118.0	120.0	119.5	119.0	117.5
			Max	134	139	145	145	145

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Systolic Blood Pressure [mmHg]	Day 22	3 hours	n	12	11	12	35	104
			Mean (SD)	119.4 (12.5)	120.7 (9.7)	127.5 (14.4)	122.6 (12.6)	118.0 (12.6)
			Min	101	107	108	101	81
			Median	117.0	118.0	130.0	118.0	117.0
			Max	147	140	149	149	149
		6 hours	n	12	11	12	35	104
			Mean (SD)	122.8 (10.9)	118.0 (8.2)	128.8 (18.2)	123.3 (13.6)	118.3 (12.8)
			Min	112	101	104	101	80
			Median	119.5	118.0	128.5	121.0	118.0
			Max	148	134	160	160	160
	Day 29		n	12	12	11	35	116
			Mean (SD)	125.8 (12.1)	124.1 (8.5)	128.0 (9.9)	125.9 (10.1)	120.0 (12.6)
			Min	110	107	116	107	90
			Median	123.5	124.0	125.0	125.0	119.5
			Max	154	141	142	154	154

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Systolic Blood Pressure [mmHg]	Day 43		n	11	12	0	23	103
			Mean (SD)	130.0 (11.9)	124.7 (8.4)	- (-)	127.2 (10.4)	120.4 (12.5)
			Min	105	111	-	105	94
			Median	134.0	122.5	-	128.0	120.0
			Max	142	141	-	142	147
	Day 50		n	12	0	0	12	95
			Mean (SD)	127.8 (10.6)	- (-)	- (-)	127.8 (10.6)	118.9 (12.3)
			Min	113	-	-	113	87
			Median	125.5	-	-	125.5	119.0
			Max	146	-	-	146	146
	Day 85		n	0	0	0	0	79
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	118.4 (11.8)
			Min	-	-	-	-	88
			Median	-	-	-	-	119.0
			Max	-	-	-	-	140

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Systolic Blood Pressure [mmHg]	Day 184		n	0	0	0	0	5
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	124.4 (19.5)
			Min	-	-	-	-	101
			Median	-	-	-	-	120.0
			Max	-	-	-	-	151
Temperature [°C]	Day -30 to 0		n	12	12	12	36	120
			Mean (SD)	36.32 (0.30)	36.38 (0.31)	36.27 (0.29)	36.32 (0.30)	36.29 (0.29)
			Min	35.9	36.0	35.7	35.7	35.7
			Median	36.30	36.40	36.30	36.35	36.20
			Max	36.8	36.9	36.6	36.9	37.0
	Day 1	Predose	n	12	12	12	36	120
			Mean (SD)	36.37 (0.23)	36.37 (0.38)	36.11 (0.24)	36.28 (0.31)	36.28 (0.28)
			Min	36.1	35.7	35.7	35.7	35.7
			Median	36.30	36.50	36.10	36.30	36.30
			Max	37.0	37.0	36.5	37.0	37.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Temperature [°C]	Day 1	1 hour	n	12	12	12	36	120
			Mean (SD)	36.28 (0.27)	36.12 (0.24)	36.23 (0.42)	36.21 (0.32)	36.23 (0.30)
			Min	35.9	35.9	35.6	35.6	35.6
			Median	36.25	36.10	36.15	36.15	36.20
			Max	36.9	36.6	37.2	37.2	37.2
		3 hours	n	12	12	12	36	120
			Mean (SD)	36.28 (0.22)	36.35 (0.38)	36.08 (0.44)	36.24 (0.37)	36.29 (0.34)
			Min	36.0	35.8	35.6	35.6	35.6
			Median	36.25	36.45	35.85	36.20	36.30
			Max	36.7	36.9	36.9	36.9	37.0
		6 hours	n	12	12	12	36	120
			Mean (SD)	36.06 (0.26)	36.54 (0.30)	36.22 (0.37)	36.27 (0.37)	36.32 (0.36)
			Min	35.6	35.9	35.6	35.6	35.5
			Median	36.05	36.60	36.25	36.30	36.30
			Max	36.5	37.0	36.7	37.0	37.1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Temperature [°C]	Day 2		n	12	12	12	36	120
			Mean (SD)	36.60 (0.57)	36.88 (0.34)	36.67 (0.52)	36.71 (0.49)	36.72 (0.52)
			Min	36.0	36.5	35.7	35.7	35.7
			Median	36.40	36.80	36.60	36.60	36.60
			Max	37.9	37.6	37.3	37.9	38.0
	Day 8		n	12	12	12	36	119
			Mean (SD)	36.12 (0.26)	36.31 (0.33)	35.98 (0.34)	36.13 (0.33)	36.18 (0.31)
			Min	35.6	35.7	35.5	35.5	35.5
			Median	36.10	36.25	36.05	36.10	36.10
			Max	36.7	36.9	36.5	36.9	36.9
	Day 22	Predose	n	12	12	12	36	117
			Mean (SD)	36.38 (0.24)	36.29 (0.30)	36.33 (0.35)	36.33 (0.29)	36.22 (0.31)
			Min	36.1	35.9	35.5	35.5	35.5
			Median	36.40	36.30	36.40	36.40	36.20
			Max	37.0	36.8	36.8	37.0	37.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Temperature [°C]	Day 22	1 hour	n	12	11	12	35	104
			Mean (SD)	35.98 (0.32)	36.02 (0.23)	36.32 (0.22)	36.11 (0.30)	36.19 (0.31)
			Min	35.7	35.5	36.1	35.5	35.5
			Median	35.90	36.00	36.30	36.10	36.10
			Max	36.8	36.3	36.8	36.8	37.2
		3 hours	n	12	11	12	35	104
			Mean (SD)	36.13 (0.32)	36.22 (0.26)	36.21 (0.18)	36.18 (0.26)	36.21 (0.28)
			Min	35.5	35.7	35.9	35.5	35.5
			Median	36.25	36.30	36.20	36.20	36.25
			Max	36.5	36.6	36.6	36.6	36.9
		6 hours	n	12	11	12	35	104
			Mean (SD)	36.23 (0.25)	36.34 (0.43)	36.18 (0.46)	36.25 (0.39)	36.33 (0.35)
			Min	35.7	35.5	35.3	35.3	35.3
			Median	36.30	36.50	36.15	36.30	36.30
			Max	36.6	36.8	36.9	36.9	37.3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Temperature [°C]	Day 29		n	12	12	11	35	116
			Mean (SD)	36.38 (0.24)	36.17 (0.26)	36.06 (0.34)	36.21 (0.30)	36.24 (0.28)
			Min	36.0	35.7	35.5	35.5	35.5
			Median	36.35	36.15	36.20	36.20	36.20
			Max	36.9	36.7	36.6	36.9	36.9
	Day 43		n	12	12	0	24	104
			Mean (SD)	36.37 (0.36)	36.36 (0.22)	- (-)	36.36 (0.29)	36.27 (0.36)
			Min	35.7	35.9	-	35.7	35.5
			Median	36.40	36.30	-	36.30	36.30
			Max	36.9	36.6	-	36.9	37.2
	Day 50		n	12	0	0	12	95
			Mean (SD)	36.30 (0.22)	- (-)	- (-)	36.30 (0.22)	36.17 (0.31)
			Min	36.0	-	-	36.0	35.5
			Median	36.25	-	-	36.25	36.10
			Max	36.7	-	-	36.7	37.1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-1: Vital signs: Descriptive statistics - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=120)
Temperature [°C]	Day 85		n	0	0	0	0	79
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	36.35 (0.29)
			Min	-	-	-	-	35.8
			Median	-	-	-	-	36.30
			Max	-	-	-	-	36.9
	Day 184		n	0	0	0	0	5
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	36.18 (0.41)
			Min	-	-	-	-	35.7
			Median	-	-	-	-	36.10
			Max	-	-	-	-	36.6

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

Program: Tfsaf_VS_3_1.sas (Page 54 of 54)

Table 14.3.2-3.3-1: Vital signs: Abnormal and clinically significant values per visit - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Diastolic Blood Pressure [mmHg]	Day -30 to 0		Abnormal (not CS)	1 (8)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	1 (8)	5 (6)
			Normal	11 (92)	12 (100)	11 (92)	12 (100)	11 (92)	11 (92)	11 (92)	79 (94)
	Day 1	Predose	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (2)
			Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	10 (83)	12 (100)	82 (98)
		1 hour	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
			Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
		3 hours	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
		6 hours	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 2		Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 8		Abnormal (not CS)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
			Normal	12 (100)	9 (75)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	81 (96)
	Day 22	Predose	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	12 (100)	11 (92)	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	80 (95)
		1 hour	Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	0 (0)	69 (82)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-3.3-1: Vital signs: Abnormal and clinically significant values per visit - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Diastolic Blood Pressure [mmHg]	Day 22	3 hours	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
			Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	0 (0)	69 (82)
		6 hours	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
			Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	0 (0)	69 (82)
	Day 29		Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	3 (4)
			Normal	12 (100)	11 (92)	11 (92)	10 (83)	12 (100)	10 (83)	12 (100)	78 (93)
	Day 43		Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	12 (100)	11 (92)	11 (92)	10 (83)	12 (100)	11 (92)	12 (100)	79 (94)
	Day 50		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
			Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	82 (98)
	Day 85		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (2)
			Normal	12 (100)	12 (100)	11 (92)	10 (83)	11 (92)	10 (83)	11 (92)	77 (92)
	Day 184		Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	0 (0)	0 (0)	4 (33)	0 (0)	0 (0)	0 (0)	0 (0)	4 (5)
Pulse Rate [beats/min]	Day -30 to 0		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	83 (99)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-3.3-1: Vital signs: Abnormal and clinically significant values per visit - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Pulse Rate [beats/min]	Day 1	Predose	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
			Normal	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	82 (98)
		1 hour	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
			Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
		3 hours	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
			Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	83 (99)
		6 hours	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 2		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 8		Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	2 (17)	4 (5)
			Normal	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	10 (83)	79 (94)
	Day 22	Predose	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (2)
			Normal	12 (100)	12 (100)	10 (83)	11 (92)	11 (92)	11 (92)	12 (100)	79 (94)
		1 hour	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	12 (100)	12 (100)	10 (83)	11 (92)	12 (100)	11 (92)	0 (0)	68 (81)
		3 hours	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
			Normal	12 (100)	12 (100)	10 (83)	11 (92)	12 (100)	10 (83)	0 (0)	67 (80)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-3.3-1: Vital signs: Abnormal and clinically significant values per visit - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Pulse Rate [beats/min]	Day 22	6 hours	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
			Normal	12 (100)	12 (100)	9 (75)	11 (92)	12 (100)	11 (92)	0 (0)	67 (80)
	Day 29		Abnormal (not CS)	0 (0)	1 (8)	2 (17)	0 (0)	0 (0)	1 (8)	0 (0)	4 (5)
			Normal	12 (100)	11 (92)	9 (75)	11 (92)	12 (100)	10 (83)	12 (100)	77 (92)
	Day 43		Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	2 (2)
			Normal	11 (92)	12 (100)	11 (92)	10 (83)	12 (100)	10 (83)	12 (100)	78 (93)
	Day 50		Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	2 (17)	3 (4)
			Normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	10 (83)	80 (95)
	Day 85		Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	0 (0)	3 (4)
			Normal	12 (100)	12 (100)	10 (83)	10 (83)	10 (83)	10 (83)	12 (100)	76 (90)
	Day 184		Normal	0 (0)	0 (0)	5 (42)	0 (0)	0 (0)	0 (0)	0 (0)	5 (6)
Respiratory Rate [breaths/min]	Day -30 to 0		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 1	Predose	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
		1 hour	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
		3 hours	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
		6 hours	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-3.3-1: Vital signs: Abnormal and clinically significant values per visit - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Respiratory Rate [breaths/min]	Day 2		Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	0 (0)	2 (17)	5 (6)
			Normal	12 (100)	12 (100)	11 (92)	12 (100)	10 (83)	12 (100)	10 (83)	79 (94)
	Day 8		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 22	Predose	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
			Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	81 (96)
		1 hour	Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	0 (0)	69 (82)
		3 hours	Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	0 (0)	69 (82)
		6 hours	Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	0 (0)	69 (82)
	Day 29		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
			Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	10 (83)	12 (100)	80 (95)
	Day 43		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
			Normal	12 (100)	12 (100)	11 (92)	10 (83)	12 (100)	11 (92)	12 (100)	80 (95)
	Day 50		Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 85		Normal	12 (100)	12 (100)	11 (92)	10 (83)	11 (92)	11 (92)	12 (100)	79 (94)
	Day 184		Normal	0 (0)	0 (0)	5 (42)	0 (0)	0 (0)	0 (0)	0 (0)	5 (6)
Systolic Blood Pressure [mmHg]	Day -30 to 0		Abnormal (not CS)	1 (8)	1 (8)	1 (8)	0 (0)	3 (25)	0 (0)	0 (0)	6 (7)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.2-3.3-1: Vital signs: Abnormal and clinically significant values per visit - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Systolic Blood Pressure [mmHg]	Day -30 to 0		Normal	11 (92)	11 (92)	11 (92)	12 (100)	9 (75)	12 (100)	12 (100)	78 (93)
	Day 1	Predose	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	3 (4)
			Normal	11 (92)	11 (92)	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	81 (96)
		1 hour	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (2)
			Normal	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	82 (98)
		3 hours	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	83 (99)
		6 hours	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (1)
			Normal	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	83 (99)
	Day 2		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
			Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 8		Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	12 (100)	11 (92)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	82 (98)
	Day 22	Predose	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	12 (100)	12 (100)	11 (92)	10 (83)	12 (100)	11 (92)	12 (100)	80 (95)
		1 hour	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-3.3-1: Vital signs: Abnormal and clinically significant values per visit - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Systolic Blood Pressure [mmHg]	Day 22	1 hour	Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	10 (83)	0 (0)	68 (81)
		3 hours	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	1 (8)	0 (0)	3 (4)
			Normal	12 (100)	12 (100)	10 (83)	10 (83)	12 (100)	10 (83)	0 (0)	66 (79)
		6 hours	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (17)	0 (0)	4 (5)
			Normal	12 (100)	12 (100)	10 (83)	10 (83)	12 (100)	9 (75)	0 (0)	65 (77)
	Day 29		Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	1 (8)	0 (0)	3 (4)
			Normal	12 (100)	12 (100)	10 (83)	10 (83)	12 (100)	10 (83)	12 (100)	78 (93)
	Day 43		Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	2 (2)
			Normal	12 (100)	11 (92)	11 (92)	10 (83)	11 (92)	11 (92)	12 (100)	78 (93)
	Day 50		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	2 (2)
			Normal	11 (92)	12 (100)	12 (100)	11 (92)	12 (100)	11 (92)	12 (100)	81 (96)
	Day 85		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (1)
			Normal	12 (100)	12 (100)	11 (92)	10 (83)	11 (92)	10 (83)	12 (100)	78 (93)
	Day 184		Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	0 (0)	0 (0)	4 (33)	0 (0)	0 (0)	0 (0)	0 (0)	4 (5)
Temperature [°C]	Day -30 to 0		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-3.3-1: Vital signs: Abnormal and clinically significant values per visit - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Temperature [°C]	Day 1	Predose	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
		1 hour	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
		3 hours	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
		6 hours	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	84 (100)
	Day 2		CS abnormal	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	3 (25)	5 (6)
			Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (17)	4 (5)
			Normal	12 (100)	12 (100)	11 (92)	12 (100)	11 (92)	10 (83)	7 (58)	75 (89)
	Day 8		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 22	Predose	Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	81 (96)
		1 hour	Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	0 (0)	69 (82)
			Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		3 hours	Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	0 (0)	69 (82)
			Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		6 hours	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
			Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	0 (0)	69 (82)
			Missing	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_VS_3_3.sas (Page 8 of 18)

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.2-3.3-1: Vital signs: Abnormal and clinically significant values per visit - BNT162b1

Safety set

				Younger dose ranging cohorts							
Parameter [Unit]	Visit	Timepoint		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	50 µg (N=12) n (%)	60 µg (N=12) n (%)	Total (N=84) n (%)
Temperature [°C]	Day 29		Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	81 (96)
	Day 43		Normal	12 (100)	12 (100)	11 (92)	10 (83)	12 (100)	11 (92)	12 (100)	80 (95)
	Day 50		Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	83 (99)
	Day 85		Normal	12 (100)	12 (100)	11 (92)	10 (83)	11 (92)	11 (92)	12 (100)	79 (94)
	Day 184		Normal	0 (0)	0 (0)	5 (42)	0 (0)	0 (0)	0 (0)	0 (0)	5 (6)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-3.3-1: Vital signs: Abnormal and clinically significant values per visit - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Diastolic Blood Pressure [mmHg]	Day -30 to 0		Abnormal (not CS)	0 (0)	0 (0)	2 (17)	2 (6)	7 (6)
			Normal	12 (100)	12 (100)	10 (83)	34 (94)	113 (94)
	Day 1	Predose	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	2 (6)	4 (3)
			Normal	12 (100)	12 (100)	10 (83)	34 (94)	116 (97)
		1 hour	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
			Normal	12 (100)	12 (100)	11 (92)	35 (97)	119 (99)
		3 hours	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)
		6 hours	Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	Day 2		Abnormal (not CS)	2 (17)	0 (0)	2 (17)	4 (11)	5 (4)
			Normal	10 (83)	12 (100)	10 (83)	32 (89)	115 (96)
	Day 8		Abnormal (not CS)	1 (8)	0 (0)	2 (17)	3 (8)	5 (4)
			Normal	11 (92)	12 (100)	10 (83)	33 (92)	114 (95)
	Day 22	Predose	Abnormal (not CS)	2 (17)	0 (0)	1 (8)	3 (8)	4 (3)
			Normal	10 (83)	12 (100)	11 (92)	33 (92)	113 (94)
		1 hour	Normal	12 (100)	11 (92)	12 (100)	35 (97)	104 (87)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_VS_3_3.sas (Page 10 of 18)

Table 14.3.2-3.3-1: Vital signs: Abnormal and clinically significant values per visit - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Diastolic Blood Pressure [mmHg]	Day 22	3 hours	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
			Normal	11 (92)	11 (92)	11 (92)	33 (92)	102 (85)
		6 hours	Abnormal (not CS)	2 (17)	0 (0)	1 (8)	3 (8)	3 (3)
			Normal	10 (83)	11 (92)	11 (92)	32 (89)	101 (84)
	Day 29		Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	4 (3)
			Normal	11 (92)	12 (100)	11 (92)	34 (94)	112 (93)
	Day 43		Abnormal (not CS)	2 (17)	0 (0)	0 (0)	2 (6)	3 (3)
			Normal	9 (75)	12 (100)	0 (0)	21 (58)	100 (83)
	Day 50		Abnormal (not CS)	2 (17)	0 (0)	0 (0)	2 (6)	3 (3)
			Normal	10 (83)	0 (0)	0 (0)	10 (28)	92 (77)
	Day 85		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
			Normal	0 (0)	0 (0)	0 (0)	0 (0)	77 (64)
	Day 184		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Pulse Rate [beats/min]	Day -30 to 0		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_VS_3_3.sas (Page 11 of 18)

Table 14.3.2-3.3-1: Vital signs: Abnormal and clinically significant values per visit - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Pulse Rate [beats/min]	Day 1	Predose	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
			Normal	12 (100)	12 (100)	12 (100)	36 (100)	118 (98)
		1 hour	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (6)	2 (2)
			Normal	11 (92)	11 (92)	12 (100)	34 (94)	118 (98)
		3 hours	Abnormal (not CS)	2 (17)	0 (0)	0 (0)	2 (6)	3 (3)
			Normal	10 (83)	12 (100)	12 (100)	34 (94)	117 (98)
		6 hours	Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	Day 2		Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	Day 8		Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	6 (5)
			Normal	11 (92)	12 (100)	11 (92)	34 (94)	113 (94)
	Day 22	Predose	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
			Normal	12 (100)	12 (100)	12 (100)	36 (100)	115 (96)
		1 hour	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	12 (100)	11 (92)	12 (100)	35 (97)	103 (86)
		3 hours	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	4 (3)
			Normal	11 (92)	11 (92)	11 (92)	33 (92)	100 (83)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_VS_3_3.sas (Page 12 of 18)

Table 14.3.2-3.3-1: Vital signs: Abnormal and clinically significant values per visit - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Pulse Rate [beats/min]	Day 22	6 hours	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
			Normal	11 (92)	11 (92)	12 (100)	34 (94)	101 (84)
	Day 29		Abnormal (not CS)	0 (0)	0 (0)	3 (25)	3 (8)	7 (6)
			Normal	12 (100)	12 (100)	8 (67)	32 (89)	109 (91)
	Day 43		Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
			Normal	8 (67)	12 (100)	0 (0)	20 (56)	98 (82)
	Day 50		Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	4 (3)
			Normal	11 (92)	0 (0)	0 (0)	11 (31)	91 (76)
	Day 85		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
			Normal	0 (0)	0 (0)	0 (0)	0 (0)	76 (63)
	Day 184		Normal	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
Respiratory Rate [breaths/min]	Day -30 to 0		Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	Day 1	Predose	Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
		1 hour	Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
		3 hours	Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
		6 hours	Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_VS_3_3.sas (Page 13 of 18)

Table 14.3.2-3.3-1: Vital signs: Abnormal and clinically significant values per visit - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Respiratory Rate [breaths/min]	Day 2		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
			Normal	12 (100)	12 (100)	12 (100)	36 (100)	115 (96)
	Day 8		Normal	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)
	Day 22	Predose	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
			Normal	12 (100)	11 (92)	12 (100)	35 (97)	116 (97)
		1 hour	Normal	12 (100)	11 (92)	12 (100)	35 (97)	104 (87)
		3 hours	Normal	12 (100)	11 (92)	12 (100)	35 (97)	104 (87)
		6 hours	Normal	12 (100)	11 (92)	12 (100)	35 (97)	104 (87)
	Day 29		Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
			Normal	12 (100)	11 (92)	11 (92)	34 (94)	114 (95)
	Day 43		Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
			Normal	11 (92)	11 (92)	0 (0)	22 (61)	102 (85)
	Day 50		Normal	12 (100)	0 (0)	0 (0)	12 (33)	95 (79)
	Day 85		Normal	0 (0)	0 (0)	0 (0)	0 (0)	79 (66)
	Day 184		Normal	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
Systolic Blood Pressure [mmHg]	Day -30 to 0		Abnormal (not CS)	0 (0)	2 (17)	2 (17)	4 (11)	10 (8)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_VS_3_3.sas (Page 14 of 18)

Table 14.3.2-3.3-1: Vital signs: Abnormal and clinically significant values per visit - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Systolic Blood Pressure [mmHg]	Day -30 to 0		Normal	12 (100)	10 (83)	10 (83)	32 (89)	110 (92)
	Day 1	Predose	Abnormal (not CS)	0 (0)	1 (8)	3 (25)	4 (11)	7 (6)
			Normal	12 (100)	11 (92)	9 (75)	32 (89)	113 (94)
		1 hour	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	3 (8)	5 (4)
			Normal	11 (92)	11 (92)	11 (92)	33 (92)	115 (96)
		3 hours	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	3 (8)	4 (3)
			Normal	11 (92)	11 (92)	11 (92)	33 (92)	116 (97)
		6 hours	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
			Normal	12 (100)	12 (100)	11 (92)	35 (97)	118 (98)
	Day 2		Abnormal (not CS)	1 (8)	0 (0)	2 (17)	3 (8)	3 (3)
			Normal	11 (92)	12 (100)	10 (83)	33 (92)	117 (98)
	Day 8		Abnormal (not CS)	2 (17)	2 (17)	2 (17)	6 (17)	7 (6)
			Normal	10 (83)	10 (83)	10 (83)	30 (83)	112 (93)
	Day 22	Predose	Abnormal (not CS)	1 (8)	0 (0)	3 (25)	4 (11)	5 (4)
			Normal	11 (92)	12 (100)	9 (75)	32 (89)	112 (93)
		1 hour	Abnormal (not CS)	0 (0)	0 (0)	3 (25)	3 (8)	4 (3)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_VS_3_3.sas (Page 15 of 18)

Table 14.3.2-3.3-1: Vital signs: Abnormal and clinically significant values per visit - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Systolic Blood Pressure [mmHg]	Day 22	1 hour	Normal	12 (100)	11 (92)	9 (75)	32 (89)	100 (83)
		3 hours	Abnormal (not CS)	1 (8)	0 (0)	3 (25)	4 (11)	7 (6)
			Normal	11 (92)	11 (92)	9 (75)	31 (86)	97 (81)
		6 hours	Abnormal (not CS)	1 (8)	0 (0)	2 (17)	3 (8)	7 (6)
			Normal	11 (92)	11 (92)	10 (83)	32 (89)	97 (81)
	Day 29		Abnormal (not CS)	1 (8)	1 (8)	2 (17)	4 (11)	7 (6)
			Normal	11 (92)	11 (92)	9 (75)	31 (86)	109 (91)
	Day 43		Abnormal (not CS)	2 (17)	1 (8)	0 (0)	3 (8)	5 (4)
			Normal	9 (75)	11 (92)	0 (0)	20 (56)	98 (82)
	Day 50		Abnormal (not CS)	2 (17)	0 (0)	0 (0)	2 (6)	4 (3)
			Normal	10 (83)	0 (0)	0 (0)	10 (28)	91 (76)
	Day 85		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	0 (0)	0 (0)	0 (0)	0 (0)	78 (65)
	Day 184		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	0 (0)	0 (0)	0 (0)	0 (0)	4 (3)
Temperature [°C]	Day -30 to 0		Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_VS_3_3.sas (Page 16 of 18)

Table 14.3.2-3.3-1: Vital signs: Abnormal and clinically significant values per visit - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Temperature [°C]	Day 1	Predose	Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
		1 hour	Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
		3 hours	Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
		6 hours	Normal	12 (100)	12 (100)	12 (100)	36 (100)	120 (100)
	Day 2		CS abnormal	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)
			Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (6)	6 (5)
			Normal	11 (92)	11 (92)	12 (100)	34 (94)	109 (91)
	Day 8		Normal	12 (100)	12 (100)	12 (100)	36 (100)	119 (99)
	Day 22	Predose	Normal	12 (100)	12 (100)	12 (100)	36 (100)	117 (98)
		1 hour	Normal	12 (100)	11 (92)	12 (100)	35 (97)	104 (87)
			Missing	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
		3 hours	Normal	12 (100)	11 (92)	12 (100)	35 (97)	104 (87)
			Missing	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
		6 hours	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
			Normal	12 (100)	11 (92)	11 (92)	34 (94)	103 (86)
			Missing	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_VS_3_3.sas (Page 17 of 18)

Table 14.3.2-3.3-1: Vital signs: Abnormal and clinically significant values per visit - BNT162b1

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=120) n (%)
Temperature [°C]	Day 29		Normal	12 (100)	12 (100)	11 (92)	35 (97)	116 (97)
	Day 43		Normal	12 (100)	12 (100)	0 (0)	24 (67)	104 (87)
	Day 50		Normal	12 (100)	0 (0)	0 (0)	12 (33)	95 (79)
	Day 85		Normal	0 (0)	0 (0)	0 (0)	0 (0)	79 (66)
	Day 184		Normal	0 (0)	0 (0)	0 (0)	0 (0)	5 (4)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Participant data listings - Notes for the reader

To harmonize data reporting across the different BNT162 clinical studies, the following terminology was harmonized in this interim clinical study report (CSR). The protocol, Statistical Analysis Plan (SAP), and the CSR Section 14 tables/figures, and the Section 16 listings use the original BioNTech terminology:

BioNTech terminology in the protocol, SAP and the CSR appendices	Harmonized terminology used in the interim CSR
Boost (dose)	Dose 2
Cohort	Dose group
Immunization	Dosing
Immunized	Dosed
Prime (dose)	Dose 1
(Trial) Subject	Participant
Trial	Study
Vaccinated	Dosed
Vaccination	Dosing
Vaccine	Investigational medicinal product

General considerations

General details:

The programming is based on SAP final version 4.0.

The last digit of the numbering of tables, figures and listings indicates the vaccine: 1 for BNT162b1, 2 for BNT162a1, 3 for BNT162b2, 4 for BNT162c2 (single dose) and 5 for BNT162c2 (prime/boost).

Some tables presenting adverse events are presented twice: once using the safety set and once using the safety boost set.

The adverse events based on solicited reporting via subjects diaries are defined in the file BNT162-01_AEs_based_on_solicited_reporting_via_subjects_diaries_v2.0 MBx_SSt.

The SDTM data used was received on 03NOV2020 in the folder SDTM_Group_BC_cutoff_20201023.

The adverse events intensity was assessed on different scales:
- the 10 µg young cohort was assessed on a 3-point scale (mild, moderate, severe)
- the 1 µg, 3 µg, 20 µg and 30 µg young cohorts as well as the older cohorts were assessed on a 4-point scale (mild, moderate, severe, potentially life-threatening).

Programming details:

If a table which presents categories has any all zero rows, these rows are suppressed.

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14.1 Disposition and baseline characteristics

Table 14.1-2-3: Analysis sets - BNT162b2

Safety set

	Younger dose ranging cohorts					
	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Safety set (SAF)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
Safety boost set (SAFB)	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
Prime + 7 Days completers set (CP7)	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
Prime to Boost or Prime + 28 Days completers set (CPBP28)	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	59 (98)
Boost + 7 Days completers set (CB7)	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
Boost + 28 Days completers set (CB28)	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
Prime or Boost + 28 Days completers set (CPB28)	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	59 (98)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tbase_Disp_2.sas (Page 1 of 2)

Table 14.1-2-3: Analysis sets - BNT162b2

Safety set

	Older dose ranging cohorts				
	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Safety set (SAF)	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
Safety boost set (SAFB)	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
Prime + 7 Days completers set (CP7)	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
Prime to Boost or Prime + 28 Days completers set (CPBP28)	12 (100)	12 (100)	12 (100)	36 (100)	95 (99)
Boost + 7 Days completers set (CB7)	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
Boost + 28 Days completers set (CB28)	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
Prime or Boost + 28 Days completers set (CPB28)	12 (100)	12 (100)	12 (100)	36 (100)	95 (99)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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14.1-3 Premature discontinuation

Table 14.1-3.1-3: Premature discontinuation by group - BNT162b2

Safety set

		Younger dose ranging cohorts					
		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Reason for premature treatment discontinuation	Any	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (3)
	Adverse Event	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
	Withdrawal By Subject	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.1-3.1-3: Premature discontinuation by group - BNT162b2

Safety set

		Older dose ranging cohorts				
		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Reason for premature treatment discontinuation	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Adverse Event	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Withdrawal By Subject	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tbase_Disp_3_2.sas (Page 2 of 2)

14.1-4 Demographic characteristics

Table 14.1-4.1-3: Demographic characteristics, continuous - BNT162b2

Safety set

		Younger dose ranging cohorts					
		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Age [years]	n	12	12	12	12	12	60
	Mean (SD)	36.65 (10.14)	39.64 (10.14)	35.07 (10.46)	42.75 (9.89)	47.21 (6.43)	40.26 (10.20)
	Min	21.6	24.6	19.0	29.4	35.8	19.0
	Median	37.54	40.83	36.00	42.04	47.42	41.50
	Max	53.4	55.8	51.5	55.8	55.7	55.8
Height [cm]	n	12	12	12	12	12	60
	Mean (SD)	177.8 (9.3)	173.8 (11.5)	173.6 (9.0)	168.3 (6.8)	176.3 (10.1)	174.0 (9.7)
	Min	169	155	165	157	157	155
	Median	174.5	174.0	171.0	168.0	179.0	173.0
	Max	204	195	191	181	189	204
Weight [kg]	n	12	12	12	12	12	60
	Mean (SD)	80.18 (14.13)	77.08 (10.84)	76.11 (11.67)	72.45 (10.97)	77.78 (8.43)	76.72 (11.26)
	Min	55.7	57.2	60.6	56.9	60.6	55.7
	Median	81.50	76.35	74.65	71.40	81.40	77.30
	Max	99.1	98.0	97.1	90.2	86.0	99.1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation.

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Table 14.1-4.1-3: Demographic characteristics, continuous - BNT162b2

Safety set

		Younger dose ranging cohorts					
		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
BMI [kg/m2]	n	12	12	12	12	12	60
	Mean (SD)	25.25 (3.26)	25.50 (2.79)	25.13 (2.07)	25.43 (2.34)	25.01 (1.38)	25.27 (2.37)
	Min	19.5	22.0	22.0	21.2	22.8	19.5
	Median	24.90	24.60	24.95	25.65	25.35	25.05
	Max	29.8	29.8	29.0	29.0	27.4	29.8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation.

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Table 14.1-4.1-3: Demographic characteristics, continuous - BNT162b2

Safety set

		Older dose ranging cohorts				
		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Age [years]	n	12	12	12	36	96
	Mean (SD)	65.44 (7.42)	65.88 (6.56)	63.87 (5.42)	65.06 (6.39)	49.56 (15.01)
	Min	56.9	56.8	57.0	56.8	19.0
	Median	64.58	65.79	63.96	65.29	50.33
	Max	84.0	80.6	73.4	84.0	84.0
Height [cm]	n	12	12	12	36	96
	Mean (SD)	174.8 (7.9)	172.8 (9.9)	170.8 (8.1)	172.8 (8.6)	173.5 (9.2)
	Min	154	153	158	153	153
	Median	178.0	171.5	170.5	175.5	173.0
	Max	182	185	183	185	204
Weight [kg]	n	12	12	12	36	96
	Mean (SD)	77.87 (9.78)	76.91 (12.38)	75.80 (11.98)	76.86 (11.14)	76.77 (11.15)
	Min	55.5	57.7	60.4	55.5	55.5
	Median	78.55	77.90	78.50	78.20	77.95
	Max	91.0	101.8	94.6	101.8	101.8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation.

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Table 14.1-4.1-3: Demographic characteristics, continuous - BNT162b2

Safety set

		Older dose ranging cohorts				
		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
BMI [kg/m2]	n	12	12	12	36	96
	Mean (SD)	25.43 (2.15)	25.62 (2.47)	25.85 (2.75)	25.63 (2.40)	25.40 (2.38)
	Min	21.8	22.6	21.9	21.8	19.5
	Median	25.50	25.00	25.55	25.30	25.15
	Max	28.4	29.7	29.4	29.7	29.8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation.

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Table 14.1-4.2-3: Demographic characteristics, categorical - BNT162b2

Safety set

		Younger dose ranging cohorts					
		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Gender	Male	7 (58)	5 (42)	4 (33)	2 (17)	8 (67)	26 (43)
	Female	5 (42)	7 (58)	8 (67)	10 (83)	4 (33)	34 (57)
Ethnicity	Not Hispanic or Latino	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
Race	White	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.1-4.2-3: Demographic characteristics, categorical - BNT162b2

Safety set

		Older dose ranging cohorts				
		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Gender	Male	8 (67)	6 (50)	4 (33)	18 (50)	44 (46)
	Female	4 (33)	6 (50)	8 (67)	18 (50)	52 (54)
Ethnicity	Not Hispanic or Latino	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
Race	White	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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14.3 Safety
14.3.1 Primary endpoints

14.3.1-1 Local reactions

Table 14.3.1-1.1-3: Summary of solicited local reactions - BNT162b2

Safety set

		Younger dose ranging cohorts					
Time interval		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Prime up to Day 7 after prime	nn	12	12	12	12	12	60
	Any local reaction n (%)	6 (50)	9 (75)	12 (100)	12 (100)	10 (83)	49 (82)
Boost up to Day 7 after boost	nn	11	12	11	12	12	58
	Any local reaction n (%)	4 (36)	8 (67)	10 (91)	10 (83)	11 (92)	43 (74)
	Any grade >= 3 local reaction n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Combined interval	nn	12	12	12	12	12	60
	Any local reaction n (%)	7 (58)	10 (83)	12 (100)	12 (100)	11 (92)	52 (87)
	Any grade >= 3 local reaction n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reactions; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-1.1-3: Summary of solicited local reactions - BNT162b2

Safety set

		Older dose ranging cohorts				
Time interval		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Prime up to Day 7 after prime	nn	12	12	12	36	96
	Any local reaction n (%)	7 (58)	9 (75)	9 (75)	25 (69)	74 (77)
Boost up to Day 7 after boost	nn	12	12	12	36	94
	Any local reaction n (%)	7 (58)	8 (67)	10 (83)	25 (69)	68 (72)
	Any grade >= 3 local reaction n (%)	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
Combined interval	nn	12	12	12	36	96
	Any local reaction n (%)	9 (75)	11 (92)	11 (92)	31 (86)	83 (86)
	Any grade >= 3 local reaction n (%)	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reactions; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-1.2-3: Summary of solicited local reactions - completers only - BNT162b2

Safety set

		Younger dose ranging cohorts					
Time interval		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Prime up to Day 7 after prime	nn	12	12	12	12	12	60
	Any local reaction n (%)	6 (50)	9 (75)	12 (100)	12 (100)	10 (83)	49 (82)
Boost up to Day 7 after boost	nn	11	12	11	12	12	58
	Any local reaction n (%)	4 (36)	8 (67)	10 (91)	10 (83)	11 (92)	43 (74)
	Any grade >= 3 local reaction n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Combined interval	nn	11	12	11	12	12	58
	Any local reaction n (%)	6 (55)	10 (83)	11 (100)	12 (100)	11 (92)	50 (86)
	Any grade >= 3 local reaction n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reactions; nn = number of subjects with any information on local reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

Program: Tsaf_locR_1-2.sas (Page 1 of 2)

Table 14.3.1-1.2-3: Summary of solicited local reactions - completers only - BNT162b2

Safety set

		Older dose ranging cohorts				
Time interval		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Prime up to Day 7 after prime	nn	12	12	12	36	96
	Any local reaction n (%)	7 (58)	9 (75)	9 (75)	25 (69)	74 (77)
Boost up to Day 7 after boost	nn	12	12	12	36	94
	Any local reaction n (%)	7 (58)	8 (67)	10 (83)	25 (69)	68 (72)
	Any grade >= 3 local reaction n (%)	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
Combined interval	nn	12	12	12	36	94
	Any local reaction n (%)	9 (75)	11 (92)	11 (92)	31 (86)	81 (86)
	Any grade >= 3 local reaction n (%)	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reactions; nn = number of subjects with any information on local reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-1.3-3: Frequency of subjects with solicited local reactions by grade - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Prime up to Day 7 after prime		nn	12	12	12	12	12	60
	Any	Any n (%)	6 (50)	9 (75)	12 (100)	12 (100)	10 (83)	49 (82)
		Mild n (%)	5 (42)	8 (67)	12 (100)	11 (92)	10 (83)	46 (77)
		Moderate n (%)	2 (17)	2 (17)	6 (50)	6 (50)	3 (25)	19 (32)
	Pain	Any n (%)	4 (33)	5 (42)	12 (100)	10 (83)	8 (67)	39 (65)
		Mild n (%)	4 (33)	5 (42)	12 (100)	9 (75)	8 (67)	38 (63)
		Moderate n (%)	0 (0)	0 (0)	1 (8)	3 (25)	1 (8)	5 (8)
	Tenderness	Any n (%)	4 (33)	9 (75)	11 (92)	10 (83)	10 (83)	44 (73)
		Mild n (%)	3 (25)	8 (67)	8 (67)	8 (67)	10 (83)	37 (62)
		Moderate n (%)	2 (17)	2 (17)	6 (50)	6 (50)	3 (25)	19 (32)
	Erythema/Redness	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Induration/Swelling	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	2 (3)
		Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	2 (3)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-1.3-3: Frequency of subjects with solicited local reactions by grade - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Boost up to Day 7 after boost		nn	11	12	11	12	12	58
	Any	Any n (%)	4 (36)	8 (67)	10 (91)	10 (83)	11 (92)	43 (74)
		Mild n (%)	4 (36)	8 (67)	10 (91)	10 (83)	11 (92)	43 (74)
		Moderate n (%)	0 (0)	0 (0)	4 (36)	3 (25)	0 (0)	7 (12)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Pain	Any n (%)	2 (18)	5 (42)	10 (91)	10 (83)	9 (75)	36 (62)
		Mild n (%)	2 (18)	5 (42)	10 (91)	10 (83)	9 (75)	36 (62)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (3)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Tenderness	Any n (%)	4 (36)	7 (58)	9 (82)	10 (83)	11 (92)	41 (71)
		Mild n (%)	4 (36)	7 (58)	8 (73)	10 (83)	11 (92)	40 (69)
		Moderate n (%)	0 (0)	0 (0)	4 (36)	2 (17)	0 (0)	6 (10)
	Erythema/Redness	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
		Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-1.3-3: Frequency of subjects with solicited local reactions by grade - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Boost up to Day 7 after boost	Erythema/Redness	Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Induration/Swelling	Any n (%)	0 (0)	0 (0)	1 (9)	0 (0)	2 (17)	3 (5)
		Mild n (%)	0 (0)	0 (0)	1 (9)	0 (0)	2 (17)	3 (5)
Combined interval		nn	12	12	12	12	12	60
	Any	Any n (%)	7 (58)	10 (83)	12 (100)	12 (100)	11 (92)	52 (87)
		Mild n (%)	7 (58)	10 (83)	12 (100)	12 (100)	11 (92)	52 (87)
		Moderate n (%)	2 (17)	2 (17)	7 (58)	7 (58)	3 (25)	21 (35)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Pain	Any n (%)	5 (42)	6 (50)	12 (100)	12 (100)	10 (83)	45 (75)
		Mild n (%)	5 (42)	6 (50)	12 (100)	12 (100)	10 (83)	45 (75)
		Moderate n (%)	0 (0)	0 (0)	1 (8)	4 (33)	1 (8)	6 (10)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Tenderness	Any n (%)	5 (42)	10 (83)	12 (100)	10 (83)	11 (92)	48 (80)
		Mild n (%)	5 (42)	10 (83)	9 (75)	10 (83)	11 (92)	45 (75)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-1.3-3: Frequency of subjects with solicited local reactions by grade - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Combined interval	Tenderness	Moderate n (%)	2 (17)	2 (17)	7 (58)	6 (50)	3 (25)	20 (33)
	Erythema/Redness	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
		Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Induration/Swelling	Any n (%)	0 (0)	0 (0)	1 (8)	0 (0)	3 (25)	4 (7)
		Mild n (%)	0 (0)	0 (0)	1 (8)	0 (0)	3 (25)	4 (7)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-1.3-3: Frequency of subjects with solicited local reactions by grade - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Prime up to Day 7 after prime		nn	12	12	12	36	96
	Any	Any n (%)	7 (58)	9 (75)	9 (75)	25 (69)	74 (77)
		Mild n (%)	5 (42)	9 (75)	9 (75)	23 (64)	69 (72)
		Moderate n (%)	2 (17)	3 (25)	1 (8)	6 (17)	25 (26)
	Pain	Any n (%)	2 (17)	5 (42)	7 (58)	14 (39)	53 (55)
		Mild n (%)	2 (17)	5 (42)	7 (58)	14 (39)	52 (54)
		Moderate n (%)	0 (0)	1 (8)	0 (0)	1 (3)	6 (6)
	Tenderness	Any n (%)	6 (50)	8 (67)	8 (67)	22 (61)	66 (69)
		Mild n (%)	4 (33)	8 (67)	7 (58)	19 (53)	56 (58)
		Moderate n (%)	2 (17)	3 (25)	1 (8)	6 (17)	25 (26)
	Erythema/Redness	Any n (%)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
		Mild n (%)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Induration/Swelling	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-1.3-3: Frequency of subjects with solicited local reactions by grade - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Boost up to Day 7 after boost		nn	12	12	12	36	94
	Any	Any n (%)	7 (58)	8 (67)	10 (83)	25 (69)	68 (72)
		Mild n (%)	6 (50)	8 (67)	9 (75)	23 (64)	66 (70)
		Moderate n (%)	2 (17)	1 (8)	5 (42)	8 (22)	15 (16)
		Severe n (%)	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
	Pain	Any n (%)	4 (33)	7 (58)	8 (67)	19 (53)	55 (59)
		Mild n (%)	3 (25)	7 (58)	6 (50)	16 (44)	52 (55)
		Moderate n (%)	0 (0)	0 (0)	4 (33)	4 (11)	6 (6)
		Severe n (%)	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
	Tenderness	Any n (%)	5 (42)	7 (58)	8 (67)	20 (56)	61 (65)
		Mild n (%)	5 (42)	6 (50)	7 (58)	18 (50)	58 (62)
		Moderate n (%)	1 (8)	1 (8)	3 (25)	5 (14)	11 (12)
	Erythema/Redness	Any n (%)	1 (8)	1 (8)	2 (17)	4 (11)	5 (5)
		Mild n (%)	0 (0)	1 (8)	2 (17)	3 (8)	4 (4)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

Program: Tsaf_locR_3-4.sas (Page 6 of 8)

Table 14.3.1-1.3-3: Frequency of subjects with solicited local reactions by grade - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Boost up to Day 7 after boost	Erythema/Redness	Moderate n (%)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Induration/Swelling	Any n (%)	2 (17)	1 (8)	1 (8)	4 (11)	7 (7)
		Mild n (%)	2 (17)	1 (8)	1 (8)	4 (11)	7 (7)
Combined interval		nn	12	12	12	36	96
	Any	Any n (%)	9 (75)	11 (92)	11 (92)	31 (86)	83 (86)
		Mild n (%)	7 (58)	11 (92)	10 (83)	28 (78)	80 (83)
		Moderate n (%)	3 (25)	4 (33)	6 (50)	13 (36)	34 (35)
		Severe n (%)	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
	Pain	Any n (%)	4 (33)	9 (75)	11 (92)	24 (67)	69 (72)
		Mild n (%)	3 (25)	9 (75)	10 (83)	22 (61)	67 (70)
		Moderate n (%)	0 (0)	1 (8)	4 (33)	5 (14)	11 (11)
		Severe n (%)	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
	Tenderness	Any n (%)	8 (67)	9 (75)	9 (75)	26 (72)	74 (77)
		Mild n (%)	6 (50)	9 (75)	9 (75)	24 (67)	69 (72)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-1.3-3: Frequency of subjects with solicited local reactions by grade - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Combined interval	Tenderness	Moderate n (%)	3 (25)	4 (33)	4 (33)	11 (31)	31 (32)
	Erythema/Redness	Any n (%)	2 (17)	1 (8)	2 (17)	5 (14)	6 (6)
		Mild n (%)	1 (8)	1 (8)	2 (17)	4 (11)	5 (5)
		Moderate n (%)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Induration/Swelling	Any n (%)	2 (17)	1 (8)	1 (8)	4 (11)	8 (8)
		Mild n (%)	2 (17)	1 (8)	1 (8)	4 (11)	8 (8)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available; N/A = not available; - = not estimable.

Program: Tsaf_locR_3-4.sas (Page 8 of 8)

Table 14.3.1-1.4-3: Frequency of subjects with solicited local reactions by grade - completers only - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Prime up to Day 7 after prime		nn	12	12	12	12	12	60
	Any	Any n (%)	6 (50)	9 (75)	12 (100)	12 (100)	10 (83)	49 (82)
		Mild n (%)	5 (42)	8 (67)	12 (100)	11 (92)	10 (83)	46 (77)
		Moderate n (%)	2 (17)	2 (17)	6 (50)	6 (50)	3 (25)	19 (32)
	Pain	Any n (%)	4 (33)	5 (42)	12 (100)	10 (83)	8 (67)	39 (65)
		Mild n (%)	4 (33)	5 (42)	12 (100)	9 (75)	8 (67)	38 (63)
		Moderate n (%)	0 (0)	0 (0)	1 (8)	3 (25)	1 (8)	5 (8)
	Tenderness	Any n (%)	4 (33)	9 (75)	11 (92)	10 (83)	10 (83)	44 (73)
		Mild n (%)	3 (25)	8 (67)	8 (67)	8 (67)	10 (83)	37 (62)
		Moderate n (%)	2 (17)	2 (17)	6 (50)	6 (50)	3 (25)	19 (32)
	Erythema/Redness	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Induration/Swelling	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	2 (3)
		Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	2 (3)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

Program: Tsaf_locR_3-4.sas (Page 1 of 8)

Table 14.3.1-1.4-3: Frequency of subjects with solicited local reactions by grade - completers only - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Boost up to Day 7 after boost		nn	11	12	11	12	12	58
	Any	Any n (%)	4 (36)	8 (67)	10 (91)	10 (83)	11 (92)	43 (74)
		Mild n (%)	4 (36)	8 (67)	10 (91)	10 (83)	11 (92)	43 (74)
		Moderate n (%)	0 (0)	0 (0)	4 (36)	3 (25)	0 (0)	7 (12)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Pain	Any n (%)	2 (18)	5 (42)	10 (91)	10 (83)	9 (75)	36 (62)
		Mild n (%)	2 (18)	5 (42)	10 (91)	10 (83)	9 (75)	36 (62)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (3)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Tenderness	Any n (%)	4 (36)	7 (58)	9 (82)	10 (83)	11 (92)	41 (71)
		Mild n (%)	4 (36)	7 (58)	8 (73)	10 (83)	11 (92)	40 (69)
		Moderate n (%)	0 (0)	0 (0)	4 (36)	2 (17)	0 (0)	6 (10)
	Erythema/Redness	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
		Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

Program: Tsaf_locR_3-4.sas (Page 2 of 8)

Table 14.3.1-1.4-3: Frequency of subjects with solicited local reactions by grade - completers only - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Boost up to Day 7 after boost	Erythema/Redness	Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Induration/Swelling	Any n (%)	0 (0)	0 (0)	1 (9)	0 (0)	2 (17)	3 (5)
		Mild n (%)	0 (0)	0 (0)	1 (9)	0 (0)	2 (17)	3 (5)
Combined interval		nn	11	12	11	12	12	58
	Any	Any n (%)	6 (55)	10 (83)	11 (100)	12 (100)	11 (92)	50 (86)
		Mild n (%)	6 (55)	10 (83)	11 (100)	12 (100)	11 (92)	50 (86)
		Moderate n (%)	2 (18)	2 (17)	6 (55)	7 (58)	3 (25)	20 (34)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Pain	Any n (%)	4 (36)	6 (50)	11 (100)	12 (100)	10 (83)	43 (74)
		Mild n (%)	4 (36)	6 (50)	11 (100)	12 (100)	10 (83)	43 (74)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	4 (33)	1 (8)	5 (9)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Tenderness	Any n (%)	5 (45)	10 (83)	11 (100)	10 (83)	11 (92)	47 (81)
		Mild n (%)	5 (45)	10 (83)	9 (82)	10 (83)	11 (92)	45 (78)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-1.4-3: Frequency of subjects with solicited local reactions by grade - completers only - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Combined interval	Tenderness	Moderate n (%)	2 (18)	2 (17)	6 (55)	6 (50)	3 (25)	19 (33)
	Erythema/Redness	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
		Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Induration/Swelling	Any n (%)	0 (0)	0 (0)	1 (9)	0 (0)	3 (25)	4 (7)
		Mild n (%)	0 (0)	0 (0)	1 (9)	0 (0)	3 (25)	4 (7)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-1.4-3: Frequency of subjects with solicited local reactions by grade - completers only - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Prime up to Day 7 after prime		nn	12	12	12	36	96
	Any	Any n (%)	7 (58)	9 (75)	9 (75)	25 (69)	74 (77)
		Mild n (%)	5 (42)	9 (75)	9 (75)	23 (64)	69 (72)
		Moderate n (%)	2 (17)	3 (25)	1 (8)	6 (17)	25 (26)
	Pain	Any n (%)	2 (17)	5 (42)	7 (58)	14 (39)	53 (55)
		Mild n (%)	2 (17)	5 (42)	7 (58)	14 (39)	52 (54)
		Moderate n (%)	0 (0)	1 (8)	0 (0)	1 (3)	6 (6)
	Tenderness	Any n (%)	6 (50)	8 (67)	8 (67)	22 (61)	66 (69)
		Mild n (%)	4 (33)	8 (67)	7 (58)	19 (53)	56 (58)
		Moderate n (%)	2 (17)	3 (25)	1 (8)	6 (17)	25 (26)
	Erythema/Redness	Any n (%)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
		Mild n (%)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Induration/Swelling	Any n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Mild n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

Program: Tsaf_locR_3-4.sas (Page 5 of 8)

Table 14.3.1-1.4-3: Frequency of subjects with solicited local reactions by grade - completers only - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Boost up to Day 7 after boost		nn	12	12	12	36	94
	Any	Any n (%)	7 (58)	8 (67)	10 (83)	25 (69)	68 (72)
		Mild n (%)	6 (50)	8 (67)	9 (75)	23 (64)	66 (70)
		Moderate n (%)	2 (17)	1 (8)	5 (42)	8 (22)	15 (16)
		Severe n (%)	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
	Pain	Any n (%)	4 (33)	7 (58)	8 (67)	19 (53)	55 (59)
		Mild n (%)	3 (25)	7 (58)	6 (50)	16 (44)	52 (55)
		Moderate n (%)	0 (0)	0 (0)	4 (33)	4 (11)	6 (6)
		Severe n (%)	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
	Tenderness	Any n (%)	5 (42)	7 (58)	8 (67)	20 (56)	61 (65)
		Mild n (%)	5 (42)	6 (50)	7 (58)	18 (50)	58 (62)
		Moderate n (%)	1 (8)	1 (8)	3 (25)	5 (14)	11 (12)
	Erythema/Redness	Any n (%)	1 (8)	1 (8)	2 (17)	4 (11)	5 (5)
		Mild n (%)	0 (0)	1 (8)	2 (17)	3 (8)	4 (4)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

Program: Tsaf_locR_3-4.sas (Page 6 of 8)

Table 14.3.1-1.4-3: Frequency of subjects with solicited local reactions by grade - completers only - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Boost up to Day 7 after boost	Erythema/Redness	Moderate n (%)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Induration/Swelling	Any n (%)	2 (17)	1 (8)	1 (8)	4 (11)	7 (7)
		Mild n (%)	2 (17)	1 (8)	1 (8)	4 (11)	7 (7)
Combined interval		nn	12	12	12	36	94
	Any	Any n (%)	9 (75)	11 (92)	11 (92)	31 (86)	81 (86)
		Mild n (%)	7 (58)	11 (92)	10 (83)	28 (78)	78 (83)
		Moderate n (%)	3 (25)	4 (33)	6 (50)	13 (36)	33 (35)
		Severe n (%)	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
	Pain	Any n (%)	4 (33)	9 (75)	11 (92)	24 (67)	67 (71)
		Mild n (%)	3 (25)	9 (75)	10 (83)	22 (61)	65 (69)
		Moderate n (%)	0 (0)	1 (8)	4 (33)	5 (14)	10 (11)
		Severe n (%)	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
	Tenderness	Any n (%)	8 (67)	9 (75)	9 (75)	26 (72)	73 (78)
		Mild n (%)	6 (50)	9 (75)	9 (75)	24 (67)	69 (73)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

Program: Tsaf_locR_3-4.sas (Page 7 of 8)

Table 14.3.1-1.4-3: Frequency of subjects with solicited local reactions by grade - completers only - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Combined interval	Tenderness	Moderate n (%)	3 (25)	4 (33)	4 (33)	11 (31)	30 (32)
	Erythema/Redness	Any n (%)	2 (17)	1 (8)	2 (17)	5 (14)	6 (6)
		Mild n (%)	1 (8)	1 (8)	2 (17)	4 (11)	5 (5)
		Moderate n (%)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Induration/Swelling	Any n (%)	2 (17)	1 (8)	1 (8)	4 (11)	8 (9)
		Mild n (%)	2 (17)	1 (8)	1 (8)	4 (11)	8 (9)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective local reaction; nn = number of subjects with any information on local reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

Program: Tsaf_locR_3-4.sas (Page 8 of 8)

Table 14.3.1-1.5.1-3: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Local reactions	After prime	Time from dose to first local reaction [Days]	n	6	9	12	12	10	49
			Mean (SD)	1.0 (0.0)	1.2 (0.4)	1.1 (0.3)	1.1 (0.3)	1.1 (0.3)	1.1 (0.3)
			Min	1	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0	1.0
			Max	1	2	2	2	2	2
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
		Time from first local reaction to last local reaction [Days]	n	6	9	12	12	10	49
			Mean (SD)	1.8 (1.6)	1.4 (0.7)	2.2 (0.8)	2.4 (0.9)	2.5 (1.4)	2.1 (1.1)
			Min	1	1	1	1	1	1
			Median	1.0	1.0	2.0	2.5	2.0	2.0
			Max	5	3	3	4	6	6

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.1-3: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Local reactions	After prime	Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
	After boost	Time from dose to first local reaction [Days]	n	4	8	10	10	11	43
			Mean (SD)	1.0 (0.0)	1.1 (0.4)	1.0 (0.0)	1.2 (0.4)	1.4 (0.5)	1.2 (0.4)
			Min	1	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0	1.0
			Max	1	2	1	2	2	2
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.1-3: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Local reactions	After boost	Time from first local reaction to last local reaction [Days]	n	4	8	10	10	11	43
			Mean (SD)	2.3 (1.3)	1.6 (0.7)	2.4 (0.7)	3.3 (2.2)	2.5 (1.2)	2.5 (1.4)
			Min	1	1	1	1	1	1
			Median	2.0	1.5	2.5	2.5	2.0	2.0
			Max	4	3	3	8	4	8
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
Local or systemic reactions	After prime	Time from dose to first reaction [Days]	n	9	11	12	12	11	55
			Mean (SD)	1.2 (0.7)	1.2 (0.4)	1.0 (0.0)	1.1 (0.3)	1.2 (0.4)	1.1 (0.4)
			Min	1	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0	1.0
			Max	3	2	1	2	2	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.1-3: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Local or systemic reactions	After prime	Time from dose to first reaction with grade >= 3 [Days]	n	0	0	0	1	0	1
			Mean (SD)	- (-)	- (-)	- (-)	2.0 (-)	- (-)	2.0 (-)
			Min	-	-	-	2	-	2
			Median	-	-	-	2.0	-	2.0
			Max	-	-	-	2	-	2
		Time from first reaction to last reaction [Days]	n	9	11	12	12	11	55
			Mean (SD)	3.0 (2.7)	3.0 (1.9)	2.8 (1.5)	4.0 (1.8)	3.7 (2.5)	3.3 (2.1)
			Min	1	1	1	1	1	1
			Median	2.0	2.0	3.0	4.0	3.0	3.0
			Max	9	7	6	7	7	9
		Time from first reaction with grade >= 3 to last reaction with grade >= 3 [Days]	n	0	0	0	1	0	1
			Mean (SD)	- (-)	- (-)	- (-)	1.0 (-)	- (-)	1.0 (-)
			Min	-	-	-	1	-	1
			Median	-	-	-	1.0	-	1.0
			Max	-	-	-	1	-	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.1-3: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Local or systemic reactions	After boost	Time from dose to first reaction [Days]	n	5	9	11	12	12	49
			Mean (SD)	1.0 (0.0)	1.1 (0.3)	1.0 (0.0)	1.3 (0.5)	1.4 (0.5)	1.2 (0.4)
			Min	1	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0	1.0
			Max	1	2	1	2	2	2
		Time from dose to first reaction with grade >= 3 [Days]	n	0	0	1	1	3	5
			Mean (SD)	- (-)	- (-)	1.0 (-)	2.0 (-)	2.7 (1.2)	2.2 (1.1)
			Min	-	-	1	2	2	1
			Median	-	-	1.0	2.0	2.0	2.0
			Max	-	-	1	2	4	4
		Time from first reaction to last reaction [Days]	n	5	9	11	12	12	49
			Mean (SD)	3.2 (2.4)	3.1 (3.1)	2.5 (0.9)	3.3 (2.1)	2.6 (1.6)	2.9 (2.0)
			Min	1	1	1	1	1	1
			Median	2.0	2.0	3.0	2.5	2.5	2.0
			Max	7	9	4	8	6	9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.1-3: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Local or systemic reactions	After boost	Time from first reaction with grade >= 3 to last reaction with grade >= 3 [Days]	n	0	0	1	1	3	5
			Mean (SD)	- (-)	- (-)	1.0 (-)	1.0 (-)	1.3 (0.6)	1.2 (0.4)
			Min	-	-	1	1	1	1
			Median	-	-	1.0	1.0	1.0	1.0
			Max	-	-	1	1	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.1-3: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Local reactions	After prime	Time from dose to first local reaction [Days]	n	7	9	9	25	74
			Mean (SD)	1.3 (0.5)	1.3 (0.5)	1.2 (0.4)	1.3 (0.5)	1.2 (0.4)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	2	2	2	2	2
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from first local reaction to last local reaction [Days]	n	7	9	9	25	74
			Mean (SD)	2.3 (2.2)	1.9 (0.8)	1.9 (0.8)	2.0 (1.3)	2.1 (1.2)
			Min	1	1	1	1	1
			Median	1.0	2.0	2.0	2.0	2.0
			Max	7	3	3	7	7

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.1-3: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Local reactions	After prime	Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
	After boost	Time from dose to first local reaction [Days]	n	7	8	10	25	68
			Mean (SD)	1.3 (0.5)	1.0 (0.0)	1.2 (0.4)	1.2 (0.4)	1.2 (0.4)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	2	1	2	2	2
		Time from dose to first local reaction with grade >= 3 [Days]	n	1	0	1	2	2
			Mean (SD)	2.0 (-)	- (-)	2.0 (-)	2.0 (-)	2.0 (-)
			Min	2	-	2	2	2
			Median	2.0	-	2.0	2.0	2.0
			Max	2	-	2	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.1-3: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Local reactions	After boost	Time from first local reaction to last local reaction [Days]	n	7	8	10	25	68
			Mean (SD)	3.7 (2.1)	1.6 (0.5)	2.7 (1.2)	2.6 (1.6)	2.5 (1.5)
			Min	1	1	1	1	1
			Median	3.0	2.0	2.5	2.0	2.0
			Max	7	2	5	7	8
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	1	0	1	2	2
			Mean (SD)	1.0 (-)	- (-)	1.0 (-)	1.0 (-)	1.0 (-)
			Min	1	-	1	1	1
			Median	1.0	-	1.0	1.0	1.0
			Max	1	-	1	1	1
Local or systemic reactions	After prime	Time from dose to first reaction [Days]	n	8	9	10	27	82
			Mean (SD)	1.1 (0.4)	1.3 (0.5)	1.2 (0.4)	1.2 (0.4)	1.2 (0.4)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	2	2	2	2	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.1-3: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Local or systemic reactions	After prime	Time from dose to first reaction with grade >= 3 [Days]	n	1	0	0	1	2
			Mean (SD)	1.0 (-)	- (-)	- (-)	1.0 (-)	1.5 (-)
			Min	1	-	-	1	1
			Median	1.0	-	-	1.0	1.5
			Max	1	-	-	1	2
		Time from first reaction to last reaction [Days]	n	8	9	10	27	82
			Mean (SD)	3.5 (2.7)	2.0 (0.7)	2.8 (1.8)	2.7 (1.9)	3.1 (2.0)
			Min	1	1	1	1	1
			Median	2.5	2.0	2.5	2.0	3.0
			Max	7	3	7	7	9
		Time from first reaction with grade >= 3 to last reaction with grade >= 3 [Days]	n	1	0	0	1	2
			Mean (SD)	1.0 (-)	- (-)	- (-)	1.0 (-)	1.0 (-)
			Min	1	-	-	1	1
			Median	1.0	-	-	1.0	1.0
			Max	1	-	-	1	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.1-3: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Local or systemic reactions	After boost	Time from dose to first reaction [Days]	n	7	9	11	27	76
			Mean (SD)	1.3 (0.5)	1.0 (0.0)	1.2 (0.4)	1.1 (0.4)	1.2 (0.4)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	2	1	2	2	2
		Time from dose to first reaction with grade >= 3 [Days]	n	2	0	2	4	9
			Mean (SD)	1.5 (-)	- (-)	1.5 (-)	1.5 (0.6)	1.9 (0.9)
			Min	1	-	1	1	1
			Median	1.5	-	1.5	1.5	2.0
			Max	2	-	2	2	4
		Time from first reaction to last reaction [Days]	n	7	9	11	27	76
			Mean (SD)	4.3 (2.4)	2.9 (1.7)	2.9 (1.3)	3.3 (1.8)	3.0 (1.9)
			Min	1	2	1	1	1
			Median	4.0	2.0	3.0	3.0	2.0
			Max	7	7	5	7	9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.1-3: Descriptive statistics of time of solicited local and any solicited reactions - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Local or systemic reactions	After boost	Time from first reaction with grade >= 3 to last reaction with grade >= 3 [Days]	n	2	0	2	4	9
			Mean (SD)	1.0 (-)	- (-)	1.5 (-)	1.3 (0.5)	1.2 (0.4)
			Min	1	-	1	1	1
			Median	1.0	-	1.5	1.0	1.0
			Max	1	-	2	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-3: Descriptive statistics of time of solicited local reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Pain	Time from dose to first local reaction [Days]	n	4	5	12	10	8	39
			Mean (SD)	1.0 (0.0)	1.2 (0.4)	1.3 (0.5)	1.1 (0.3)	1.3 (0.5)	1.2 (0.4)
			Min	1	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0	1.0
			Max	1	2	2	2	2	2
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
		Time from first local reaction to last local reaction [Days]	n	4	5	12	10	8	39
			Mean (SD)	1.3 (0.5)	1.4 (0.5)	1.8 (0.8)	2.4 (1.0)	2.3 (1.4)	1.9 (1.0)
			Min	1	1	1	1	1	1
			Median	1.0	1.0	2.0	2.5	2.0	2.0
			Max	2	2	3	4	5	5

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-3: Descriptive statistics of time of solicited local reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Pain	Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
	Tenderness	Time from dose to first local reaction [Days]	n	4	9	11	10	10	44
			Mean (SD)	1.0 (0.0)	1.2 (0.4)	1.1 (0.3)	1.0 (0.0)	1.1 (0.3)	1.1 (0.3)
			Min	1	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0	1.0
			Max	1	2	2	1	2	2
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-3: Descriptive statistics of time of solicited local reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Tenderness	Time from first local reaction to last local reaction [Days]	n	4	9	11	10	10	44
			Mean (SD)	2.3 (1.9)	1.4 (0.7)	2.1 (0.8)	2.7 (0.7)	2.4 (1.5)	2.2 (1.1)
			Min	1	1	1	2	1	1
			Median	1.5	1.0	2.0	3.0	2.0	2.0
			Max	5	3	3	4	6	6
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
	Erythema/Redness	Time from dose to first local reaction [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-3: Descriptive statistics of time of solicited local reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Erythema/Redness	Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
		Time from first local reaction to last local reaction [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-3: Descriptive statistics of time of solicited local reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Induration/Swelling	Time from dose to first local reaction [Days]	n	0	0	0	0	2	2
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (-)	1.0 (-)
			Min	-	-	-	-	1	1
			Median	-	-	-	-	1.0	1.0
			Max	-	-	-	-	1	1
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
		Time from first local reaction to last local reaction [Days]	n	0	0	0	0	2	2
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.5 (-)	1.5 (-)
			Min	-	-	-	-	1	1
			Median	-	-	-	-	1.5	1.5
			Max	-	-	-	-	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-3: Descriptive statistics of time of solicited local reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Induration/Swelling	Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
After boost	Pain	Time from dose to first local reaction [Days]	n	2	5	10	10	9	36
			Mean (SD)	1.0 (-)	1.2 (0.4)	1.1 (0.3)	1.2 (0.4)	1.4 (0.5)	1.2 (0.4)
			Min	1	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0	1.0
			Max	1	2	2	2	2	2
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-3: Descriptive statistics of time of solicited local reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Pain	Time from first local reaction to last local reaction [Days]	n	2	5	10	10	9	36
			Mean (SD)	2.5 (-)	1.8 (0.4)	2.1 (0.7)	2.7 (1.1)	1.8 (0.8)	2.2 (0.9)
			Min	2	1	1	1	1	1
			Median	2.5	2.0	2.0	2.5	2.0	2.0
			Max	3	2	3	4	3	4
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
	Tenderness	Time from dose to first local reaction [Days]	n	4	7	9	10	11	41
			Mean (SD)	1.0 (0.0)	1.0 (0.0)	1.0 (0.0)	1.2 (0.4)	1.4 (0.5)	1.1 (0.4)
			Min	1	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0	1.0
			Max	1	1	1	2	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-3: Descriptive statistics of time of solicited local reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Tenderness	Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
		Time from first local reaction to last local reaction [Days]	n	4	7	9	10	11	41
			Mean (SD)	2.3 (1.3)	1.6 (0.8)	2.3 (0.9)	3.3 (2.2)	2.5 (1.2)	2.5 (1.5)
			Min	1	1	1	1	1	1
			Median	2.0	1.0	3.0	2.5	2.0	2.0
			Max	4	3	3	8	4	8
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-3: Descriptive statistics of time of solicited local reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Erythema/Redness	Time from dose to first local reaction [Days]	n	0	0	0	0	1	1
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	2.0 (-)	2.0 (-)
			Min	-	-	-	-	2	2
			Median	-	-	-	-	2.0	2.0
			Max	-	-	-	-	2	2
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
		Time from first local reaction to last local reaction [Days]	n	0	0	0	0	1	1
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (-)	1.0 (-)
			Min	-	-	-	-	1	1
			Median	-	-	-	-	1.0	1.0
			Max	-	-	-	-	1	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-3: Descriptive statistics of time of solicited local reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Erythema/Redness	Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
	Induration/Swelling	Time from dose to first local reaction [Days]	n	0	0	1	0	2	3
			Mean (SD)	- (-)	- (-)	2.0 (-)	- (-)	1.5 (-)	1.7 (0.6)
			Min	-	-	2	-	1	1
			Median	-	-	2.0	-	1.5	2.0
			Max	-	-	2	-	2	2
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-3: Descriptive statistics of time of solicited local reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Induration/Swelling	Time from first local reaction to last local reaction [Days]	n	0	0	1	0	2	3
			Mean (SD)	- (-)	- (-)	1.0 (-)	- (-)	2.0 (-)	1.7 (0.6)
			Min	-	-	1	-	2	1
			Median	-	-	1.0	-	2.0	2.0
			Max	-	-	1	-	2	2
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-3: Descriptive statistics of time of solicited local reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Pain	Time from dose to first local reaction [Days]	n	2	5	7	14	53
			Mean (SD)	1.0 (-)	1.4 (0.5)	1.3 (0.5)	1.3 (0.5)	1.2 (0.4)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	1	2	2	2	2
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from first local reaction to last local reaction [Days]	n	2	5	7	14	53
			Mean (SD)	2.0 (-)	1.8 (0.8)	1.6 (0.8)	1.7 (0.8)	1.9 (0.9)
			Min	1	1	1	1	1
			Median	2.0	2.0	1.0	1.5	2.0
			Max	3	3	3	3	5

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-3: Descriptive statistics of time of solicited local reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Pain	Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
	Tenderness	Time from dose to first local reaction [Days]	n	6	8	8	22	66
			Mean (SD)	1.3 (0.5)	1.3 (0.5)	1.3 (0.5)	1.3 (0.5)	1.2 (0.4)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	2	2	2	2	2
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-3: Descriptive statistics of time of solicited local reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Tenderness	Time from first local reaction to last local reaction [Days]	n	6	8	8	22	66
			Mean (SD)	2.0 (2.0)	1.9 (0.6)	1.9 (0.8)	1.9 (1.2)	2.1 (1.1)
			Min	1	1	1	1	1
			Median	1.0	2.0	2.0	2.0	2.0
			Max	6	3	3	6	6
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
	Erythema/Redness	Time from dose to first local reaction [Days]	n	1	0	0	1	1
			Mean (SD)	1.0 (-)	- (-)	- (-)	1.0 (-)	1.0 (-)
			Min	1	-	-	1	1
			Median	1.0	-	-	1.0	1.0
			Max	1	-	-	1	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-3: Descriptive statistics of time of solicited local reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Erythema/Redness	Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from first local reaction to last local reaction [Days]	n	1	0	0	1	1
			Mean (SD)	7.0 (-)	- (-)	- (-)	7.0 (-)	7.0 (-)
			Min	7	-	-	7	7
			Median	7.0	-	-	7.0	7.0
			Max	7	-	-	7	7
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-3: Descriptive statistics of time of solicited local reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Induration/Swelling	Time from dose to first local reaction [Days]	n	0	0	0	0	2
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (-)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	1
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from first local reaction to last local reaction [Days]	n	0	0	0	0	2
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.5 (-)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.5
			Max	-	-	-	-	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-3: Descriptive statistics of time of solicited local reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Induration/Swelling	Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
After boost	Pain	Time from dose to first local reaction [Days]	n	4	7	8	19	55
			Mean (SD)	1.5 (0.6)	1.0 (0.0)	1.3 (0.5)	1.2 (0.4)	1.2 (0.4)
			Min	1	1	1	1	1
			Median	1.5	1.0	1.0	1.0	1.0
			Max	2	1	2	2	2
		Time from dose to first local reaction with grade >= 3 [Days]	n	1	0	1	2	2
			Mean (SD)	2.0 (-)	- (-)	2.0 (-)	2.0 (-)	2.0 (-)
			Min	2	-	2	2	2
			Median	2.0	-	2.0	2.0	2.0
			Max	2	-	2	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-3: Descriptive statistics of time of solicited local reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After boost	Pain	Time from first local reaction to last local reaction [Days]	n	4	7	8	19	55
			Mean (SD)	2.3 (2.5)	1.6 (0.5)	2.0 (1.3)	1.9 (1.4)	2.1 (1.1)
			Min	1	1	1	1	1
			Median	1.0	2.0	2.0	2.0	2.0
			Max	6	2	5	6	6
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	1	0	1	2	2
			Mean (SD)	1.0 (-)	- (-)	1.0 (-)	1.0 (-)	1.0 (-)
			Min	1	-	1	1	1
			Median	1.0	-	1.0	1.0	1.0
			Max	1	-	1	1	1
	Tenderness	Time from dose to first local reaction [Days]	n	5	7	8	20	61
			Mean (SD)	1.4 (0.5)	1.0 (0.0)	1.1 (0.4)	1.2 (0.4)	1.1 (0.4)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	2	1	2	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-3: Descriptive statistics of time of solicited local reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After boost	Tenderness	Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from first local reaction to last local reaction [Days]	n	5	7	8	20	61
			Mean (SD)	3.2 (1.9)	1.7 (0.5)	2.5 (1.3)	2.4 (1.4)	2.4 (1.4)
			Min	1	1	1	1	1
			Median	3.0	2.0	2.5	2.0	2.0
			Max	6	2	5	6	8
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-1.5.2-3: Descriptive statistics of time of solicited local reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After boost	Erythema/Redness	Time from dose to first local reaction [Days]	n	1	1	2	4	5
			Mean (SD)	1.0 (-)	1.0 (-)	2.0 (-)	1.5 (0.6)	1.6 (0.5)
			Min	1	1	2	1	1
			Median	1.0	1.0	2.0	1.5	2.0
			Max	1	1	2	2	2
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from first local reaction to last local reaction [Days]	n	1	1	2	4	5
			Mean (SD)	7.0 (-)	1.0 (-)	3.0 (-)	3.5 (2.6)	3.0 (2.5)
			Min	7	1	2	1	1
			Median	7.0	1.0	3.0	3.0	2.0
			Max	7	1	4	7	7

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

Program: Tsaf_locR_5.sas (Page 20 of 22)

Table 14.3.1-1.5.2-3: Descriptive statistics of time of solicited local reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After boost	Erythema/Redness	Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
	Induration/Swelling	Time from dose to first local reaction [Days]	n	2	1	1	4	7
			Mean (SD)	1.5 (-)	1.0 (-)	2.0 (-)	1.5 (0.6)	1.6 (0.5)
			Min	1	1	2	1	1
			Median	1.5	1.0	2.0	1.5	2.0
			Max	2	1	2	2	2
		Time from dose to first local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

Program: Tsaf_locR_5.sas (Page 21 of 22)

Table 14.3.1-1.5.2-3: Descriptive statistics of time of solicited local reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After boost	Induration/Swelling	Time from first local reaction to last local reaction [Days]	n	2	1	1	4	7
			Mean (SD)	2.5 (-)	1.0 (-)	2.0 (-)	2.0 (0.8)	1.9 (0.7)
			Min	2	1	2	1	1
			Median	2.5	1.0	2.0	2.0	2.0
			Max	3	1	2	3	3
		Time from first local reaction with grade >= 3 to last local reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

Program: Tsaf_locR_5.sas (Page 22 of 22)

Table 14.3.1-1.6.1-3: Frequency of subjects with solicited local and any solicited reactions per day - BNT162b2

Safety set

			Younger dose ranging cohorts					
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Local reactions	After prime	Any n	6	9	12	12	10	49
		Day 0 n (%)	6 (100)	7 (78)	11 (92)	11 (92)	9 (90)	44 (90)
		Day 1 n (%)	2 (33)	5 (56)	10 (83)	11 (92)	9 (90)	37 (76)
		Day 2 n (%)	1 (17)	1 (11)	5 (42)	6 (50)	4 (40)	17 (35)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	1 (8)	1 (10)	2 (4)
		Day 4 n (%)	1 (17)	0 (0)	0 (0)	0 (0)	1 (10)	2 (4)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	1 (2)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	After boost	Any n	4	8	10	10	11	43
		Day 0 n (%)	4 (100)	7 (88)	10 (100)	8 (80)	7 (64)	36 (84)
		Day 1 n (%)	3 (75)	4 (50)	9 (90)	10 (100)	10 (91)	36 (84)
		Day 2 n (%)	1 (25)	2 (25)	5 (50)	5 (50)	6 (55)	19 (44)
		Day 3 n (%)	1 (25)	0 (0)	0 (0)	3 (30)	3 (27)	7 (16)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	2 (5)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	2 (5)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	2 (5)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 1 of 6)

Table 14.3.1-1.6.1-3: Frequency of subjects with solicited local and any solicited reactions per day - BNT162b2

Safety set

			Younger dose ranging cohorts					
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Local reactions	After boost	Day 7 n (%)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	1 (2)
Local or systemic reactions	After prime	Any n	9	11	12	12	11	55
		Day 0 n (%)	8 (89)	9 (82)	12 (100)	11 (92)	9 (82)	49 (89)
		Day 1 n (%)	4 (44)	10 (91)	10 (83)	11 (92)	10 (91)	45 (82)
		Day 2 n (%)	4 (44)	2 (18)	7 (58)	8 (67)	4 (36)	25 (45)
		Day 3 n (%)	1 (11)	2 (18)	1 (8)	4 (33)	1 (9)	9 (16)
		Day 4 n (%)	2 (22)	2 (18)	1 (8)	4 (33)	2 (18)	11 (20)
		Day 5 n (%)	1 (11)	2 (18)	1 (8)	3 (25)	1 (9)	8 (15)
		Day 6 n (%)	1 (11)	1 (9)	0 (0)	1 (8)	2 (18)	5 (9)
		Day 7 n (%)	1 (11)	0 (0)	0 (0)	0 (0)	1 (9)	2 (4)
	After boost	Any n	5	9	11	12	12	49
		Day 0 n (%)	5 (100)	8 (89)	11 (100)	9 (75)	7 (58)	40 (82)
		Day 1 n (%)	3 (60)	4 (44)	9 (82)	11 (92)	11 (92)	38 (78)
		Day 2 n (%)	1 (20)	2 (22)	6 (55)	6 (50)	8 (67)	23 (47)
		Day 3 n (%)	1 (20)	0 (0)	1 (9)	4 (33)	3 (25)	9 (18)
		Day 4 n (%)	1 (20)	0 (0)	0 (0)	4 (33)	1 (8)	6 (12)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 2 of 6)

Table 14.3.1-1.6.1-3: Frequency of subjects with solicited local and any solicited reactions per day - BNT162b2

Safety set

			Younger dose ranging cohorts					
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Local or systemic reactions	After boost	Day 5 n (%)	0 (0)	1 (11)	0 (0)	2 (17)	1 (8)	4 (8)
		Day 6 n (%)	1 (20)	1 (11)	0 (0)	2 (17)	0 (0)	4 (8)
		Day 7 n (%)	0 (0)	2 (22)	0 (0)	1 (8)	0 (0)	3 (6)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 3 of 6)

Table 14.3.1-1.6.1-3: Frequency of subjects with solicited local and any solicited reactions per day - BNT162b2

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=25)	Total (N=96)
Local reactions	After prime	Any n	7	9	9	25	74
		Day 0 n (%)	5 (71)	6 (67)	7 (78)	18 (72)	62 (84)
		Day 1 n (%)	5 (71)	9 (100)	7 (78)	21 (84)	58 (78)
		Day 2 n (%)	2 (29)	2 (22)	2 (22)	6 (24)	23 (31)
		Day 3 n (%)	1 (14)	0 (0)	1 (11)	2 (8)	4 (5)
		Day 4 n (%)	1 (14)	0 (0)	0 (0)	1 (4)	3 (4)
		Day 5 n (%)	1 (14)	0 (0)	0 (0)	1 (4)	2 (3)
		Day 6 n (%)	1 (14)	0 (0)	0 (0)	1 (4)	1 (1)
	After boost	Any n	7	8	10	25	68
		Day 0 n (%)	5 (71)	8 (100)	8 (80)	21 (84)	57 (84)
		Day 1 n (%)	6 (86)	5 (63)	10 (100)	21 (84)	57 (84)
		Day 2 n (%)	6 (86)	0 (0)	5 (50)	11 (44)	30 (44)
		Day 3 n (%)	3 (43)	0 (0)	2 (20)	5 (20)	12 (18)
		Day 4 n (%)	2 (29)	0 (0)	2 (20)	4 (16)	6 (9)
		Day 5 n (%)	2 (29)	0 (0)	0 (0)	2 (8)	4 (6)
		Day 6 n (%)	2 (29)	0 (0)	0 (0)	2 (8)	4 (6)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 1 of 6)

Table 14.3.1-1.6.1-3: Frequency of subjects with solicited local and any solicited reactions per day - BNT162b2

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=25)	Total (N=96)
Local reactions	After boost	Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Local or systemic reactions	After prime	Any n	8	9	10	27	82
		Day 0 n (%)	7 (88)	6 (67)	8 (80)	21 (78)	70 (85)
		Day 1 n (%)	5 (63)	9 (100)	9 (90)	23 (85)	68 (83)
		Day 2 n (%)	3 (38)	3 (33)	4 (40)	10 (37)	35 (43)
		Day 3 n (%)	2 (25)	0 (0)	1 (10)	3 (11)	12 (15)
		Day 4 n (%)	2 (25)	0 (0)	1 (10)	3 (11)	14 (17)
		Day 5 n (%)	3 (38)	0 (0)	0 (0)	3 (11)	11 (13)
		Day 6 n (%)	2 (25)	0 (0)	1 (10)	3 (11)	8 (10)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	After boost	Any n	7	9	11	27	76
		Day 0 n (%)	5 (71)	9 (100)	9 (82)	23 (85)	63 (83)
		Day 1 n (%)	6 (86)	8 (89)	11 (100)	25 (93)	63 (83)
		Day 2 n (%)	6 (86)	2 (22)	6 (55)	14 (52)	37 (49)
		Day 3 n (%)	4 (57)	1 (11)	2 (18)	7 (26)	16 (21)
		Day 4 n (%)	2 (29)	0 (0)	3 (27)	5 (19)	11 (14)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 2 of 6)

Table 14.3.1-1.6.1-3: Frequency of subjects with solicited local and any solicited reactions per day - BNT162b2

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=25)	Total (N=96)
Local or systemic reactions	After boost	Day 5 n (%)	2 (29)	0 (0)	0 (0)	2 (7)	6 (8)
		Day 6 n (%)	3 (43)	1 (11)	0 (0)	4 (15)	8 (11)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (4)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 3 of 6)

Table 14.3.1-1.6.2-3: Frequency of subjects with solicited local reactions by term per day - BNT162b2

Safety set

			Younger dose ranging cohorts					
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Pain	Any n	4	5	12	10	8	39
		Day 0 n (%)	4 (100)	4 (80)	9 (75)	9 (90)	6 (75)	32 (82)
		Day 1 n (%)	1 (25)	3 (60)	9 (75)	9 (90)	7 (88)	29 (74)
		Day 2 n (%)	0 (0)	0 (0)	3 (25)	5 (50)	3 (38)	11 (28)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	1 (10)	1 (13)	2 (5)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)	1 (3)
	Tenderness	Any n	4	9	11	10	10	44
		Day 0 n (%)	4 (100)	7 (78)	10 (91)	10 (100)	9 (90)	40 (91)
		Day 1 n (%)	2 (50)	5 (56)	9 (82)	10 (100)	8 (80)	34 (77)
		Day 2 n (%)	1 (25)	1 (11)	4 (36)	6 (60)	4 (40)	16 (36)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	1 (10)	1 (10)	2 (5)
		Day 4 n (%)	1 (25)	0 (0)	0 (0)	0 (0)	1 (10)	2 (5)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	1 (2)
	Erythema/Redness	Any n	0	0	0	0	0	0
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 1 of 8)

Table 14.3.1-1.6.2-3: Frequency of subjects with solicited local reactions by term per day - BNT162b2

Safety set

			Younger dose ranging cohorts					
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Erythema/Redness	Day 2 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Induration/Swelling	Any n	0	0	0	0	2	2
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (100)	2 (100)
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (50)	1 (50)
After boost	Pain	Any n	2	5	10	10	9	36
		Day 0 n (%)	2 (100)	4 (80)	9 (90)	8 (80)	5 (56)	28 (78)
		Day 1 n (%)	2 (100)	4 (80)	9 (90)	10 (100)	8 (89)	33 (92)
		Day 2 n (%)	1 (50)	1 (20)	3 (30)	5 (50)	3 (33)	13 (36)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	3 (30)	0 (0)	3 (8)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	1 (3)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 2 of 8)

Table 14.3.1-1.6.2-3: Frequency of subjects with solicited local reactions by term per day - BNT162b2

Safety set

			Younger dose ranging cohorts					
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Tenderness	Any n	4	7	9	10	11	41
		Day 0 n (%)	4 (100)	7 (100)	9 (100)	8 (80)	7 (64)	35 (85)
		Day 1 n (%)	3 (75)	3 (43)	7 (78)	10 (100)	10 (91)	33 (80)
		Day 2 n (%)	1 (25)	1 (14)	5 (56)	5 (50)	6 (55)	18 (44)
		Day 3 n (%)	1 (25)	0 (0)	0 (0)	3 (30)	3 (27)	7 (17)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	2 (5)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	2 (5)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	2 (5)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	1 (2)
	Erythema/Redness	Any n	0	0	0	0	1	1
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	1 (100)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 3 of 8)

Table 14.3.1-1.6.2-3: Frequency of subjects with solicited local reactions by term per day - BNT162b2

Safety set

			Younger dose ranging cohorts					
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Erythema/Redness	Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Induration/Swelling	Any n	0	0	1	0	2	3
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (50)	1 (33)
		Day 1 n (%)	0 (0)	0 (0)	1 (100)	0 (0)	2 (100)	3 (100)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (50)	1 (33)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 4 of 8)

Table 14.3.1-1.6.2-3: Frequency of subjects with solicited local reactions by term per day - BNT162b2

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=25)	Total (N=96)
After prime	Pain	Any n	2	5	7	14	53
		Day 0 n (%)	2 (100)	3 (60)	5 (71)	10 (71)	42 (79)
		Day 1 n (%)	1 (50)	5 (100)	4 (57)	10 (71)	39 (74)
		Day 2 n (%)	1 (50)	1 (20)	1 (14)	3 (21)	14 (26)
		Day 3 n (%)	0 (0)	0 (0)	1 (14)	1 (7)	3 (6)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
	Tenderness	Any n	6	8	8	22	66
		Day 0 n (%)	4 (67)	6 (75)	6 (75)	16 (73)	56 (85)
		Day 1 n (%)	4 (67)	8 (100)	6 (75)	18 (82)	52 (79)
		Day 2 n (%)	1 (17)	1 (13)	2 (25)	4 (18)	20 (30)
		Day 3 n (%)	1 (17)	0 (0)	1 (13)	2 (9)	4 (6)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (3)
		Day 5 n (%)	1 (17)	0 (0)	0 (0)	1 (5)	2 (3)
	Erythema/Redness	Any n	1	0	0	1	1
		Day 0 n (%)	1 (100)	0 (0)	0 (0)	1 (100)	1 (100)
		Day 1 n (%)	1 (100)	0 (0)	0 (0)	1 (100)	1 (100)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 5 of 8)

Table 14.3.1-1.6.2-3: Frequency of subjects with solicited local reactions by term per day - BNT162b2

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=25)	Total (N=96)
After prime	Erythema/Redness	Day 2 n (%)	1 (100)	0 (0)	0 (0)	1 (100)	1 (100)
		Day 3 n (%)	1 (100)	0 (0)	0 (0)	1 (100)	1 (100)
		Day 4 n (%)	1 (100)	0 (0)	0 (0)	1 (100)	1 (100)
		Day 5 n (%)	1 (100)	0 (0)	0 (0)	1 (100)	1 (100)
		Day 6 n (%)	1 (100)	0 (0)	0 (0)	1 (100)	1 (100)
	Induration/Swelling	Any n	0	0	0	0	2
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (100)
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (50)
After boost	Pain	Any n	4	7	8	19	55
		Day 0 n (%)	2 (50)	7 (100)	6 (75)	15 (79)	43 (78)
		Day 1 n (%)	2 (50)	4 (57)	7 (88)	13 (68)	46 (84)
		Day 2 n (%)	1 (25)	0 (0)	1 (13)	2 (11)	15 (27)
		Day 3 n (%)	1 (25)	0 (0)	1 (13)	2 (11)	5 (9)
		Day 4 n (%)	1 (25)	0 (0)	1 (13)	2 (11)	3 (5)
		Day 5 n (%)	1 (25)	0 (0)	0 (0)	1 (5)	1 (2)
		Day 6 n (%)	1 (25)	0 (0)	0 (0)	1 (5)	1 (2)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 6 of 8)

Table 14.3.1-1.6.2-3: Frequency of subjects with solicited local reactions by term per day - BNT162b2

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=25)	Total (N=96)
After boost	Tenderness	Any n	5	7	8	20	61
		Day 0 n (%)	3 (60)	7 (100)	7 (88)	17 (85)	52 (85)
		Day 1 n (%)	5 (100)	5 (71)	6 (75)	16 (80)	49 (80)
		Day 2 n (%)	3 (60)	0 (0)	5 (63)	8 (40)	26 (43)
		Day 3 n (%)	2 (40)	0 (0)	1 (13)	3 (15)	10 (16)
		Day 4 n (%)	1 (20)	0 (0)	1 (13)	2 (10)	4 (7)
		Day 5 n (%)	1 (20)	0 (0)	0 (0)	1 (5)	3 (5)
		Day 6 n (%)	1 (20)	0 (0)	0 (0)	1 (5)	3 (5)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
	Erythema/Redness	Any n	1	1	2	4	5
		Day 0 n (%)	1 (100)	1 (100)	0 (0)	2 (50)	2 (40)
		Day 1 n (%)	1 (100)	0 (0)	2 (100)	3 (75)	4 (80)
		Day 2 n (%)	1 (100)	0 (0)	2 (100)	3 (75)	3 (60)
		Day 3 n (%)	1 (100)	0 (0)	1 (50)	2 (50)	2 (40)
		Day 4 n (%)	1 (100)	0 (0)	1 (50)	2 (50)	2 (40)
		Day 5 n (%)	1 (100)	0 (0)	0 (0)	1 (25)	1 (20)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 7 of 8)

Table 14.3.1-1.6.2-3: Frequency of subjects with solicited local reactions by term per day - BNT162b2

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=25)	Total (N=96)
After boost	Erythema/Redness	Day 6 n (%)	1 (100)	0 (0)	0 (0)	1 (25)	1 (20)
	Induration/Swelling	Any n	2	1	1	4	7
		Day 0 n (%)	1 (50)	1 (100)	0 (0)	2 (50)	3 (43)
		Day 1 n (%)	2 (100)	0 (0)	1 (100)	3 (75)	6 (86)
		Day 2 n (%)	2 (100)	0 (0)	1 (100)	3 (75)	4 (57)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_locR_6.sas (Page 8 of 8)

14.3.1-2 Systemic reactions

Table 14.3.1-2.1-3: Summary of solicited systemic reactions - BNT162b2

Safety set

		Younger dose ranging cohorts					
Time interval		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Prime up to Day 7 after prime	nn	12	12	12	12	12	60
	Any systemic reaction n (%)	9 (75)	9 (75)	12 (100)	9 (75)	9 (75)	48 (80)
	Any grade >= 3 systemic reaction n (%)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Boost up to Day 7 after boost	nn	11	12	11	12	12	58
	Any systemic reaction n (%)	4 (36)	2 (17)	7 (64)	10 (83)	10 (83)	33 (57)
	Any grade >= 3 systemic reaction n (%)	0 (0)	0 (0)	1 (9)	1 (8)	3 (25)	5 (9)
Combined interval	nn	12	12	12	12	12	60
	Any systemic reaction n (%)	9 (75)	9 (75)	12 (100)	11 (92)	12 (100)	53 (88)
	Any grade >= 3 systemic reaction n (%)	0 (0)	0 (0)	1 (8)	2 (17)	3 (25)	6 (10)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reactions; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_1-2.sas (Page 1 of 2)

Table 14.3.1-2.1-3: Summary of solicited systemic reactions - BNT162b2

Safety set

		Older dose ranging cohorts				
Time interval		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Prime up to Day 7 after prime	nn	12	12	12	36	96
	Any systemic reaction n (%)	3 (25)	4 (33)	9 (75)	16 (44)	64 (67)
	Any grade >= 3 systemic reaction n (%)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Boost up to Day 7 after boost	nn	12	12	12	36	94
	Any systemic reaction n (%)	4 (33)	8 (67)	11 (92)	23 (64)	56 (60)
	Any grade >= 3 systemic reaction n (%)	1 (8)	0 (0)	2 (17)	3 (8)	8 (9)
Combined interval	nn	12	12	12	36	96
	Any systemic reaction n (%)	5 (42)	10 (83)	11 (92)	26 (72)	79 (82)
	Any grade >= 3 systemic reaction n (%)	2 (17)	0 (0)	2 (17)	4 (11)	10 (10)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reactions; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_1-2.sas (Page 2 of 2)

Table 14.3.1-2.2-3: Summary of solicited systemic reactions - completers only - BNT162b2

Safety set

		Younger dose ranging cohorts					
Time interval		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Prime up to Day 7 after prime	nn	12	12	12	12	12	60
	Any systemic reaction n (%)	9 (75)	9 (75)	12 (100)	9 (75)	9 (75)	48 (80)
	Any grade >= 3 systemic reaction n (%)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Boost up to Day 7 after boost	nn	11	12	11	12	12	58
	Any systemic reaction n (%)	4 (36)	2 (17)	7 (64)	10 (83)	10 (83)	33 (57)
	Any grade >= 3 systemic reaction n (%)	0 (0)	0 (0)	1 (9)	1 (8)	3 (25)	5 (9)
Combined interval	nn	11	12	11	12	12	58
	Any systemic reaction n (%)	8 (73)	9 (75)	11 (100)	11 (92)	12 (100)	51 (88)
	Any grade >= 3 systemic reaction n (%)	0 (0)	0 (0)	1 (9)	2 (17)	3 (25)	6 (10)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reactions; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

Program: Tsaf_sysR_1-2.sas (Page 1 of 2)

Table 14.3.1-2.2-3: Summary of solicited systemic reactions - completers only - BNT162b2

Safety set

		Older dose ranging cohorts				
Time interval		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Prime up to Day 7 after prime	nn	12	12	12	36	96
	Any systemic reaction n (%)	3 (25)	4 (33)	9 (75)	16 (44)	64 (67)
	Any grade >= 3 systemic reaction n (%)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Boost up to Day 7 after boost	nn	12	12	12	36	94
	Any systemic reaction n (%)	4 (33)	8 (67)	11 (92)	23 (64)	56 (60)
	Any grade >= 3 systemic reaction n (%)	1 (8)	0 (0)	2 (17)	3 (8)	8 (9)
Combined interval	nn	12	12	12	36	94
	Any systemic reaction n (%)	5 (42)	10 (83)	11 (92)	26 (72)	77 (82)
	Any grade >= 3 systemic reaction n (%)	2 (17)	0 (0)	2 (17)	4 (11)	10 (11)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reactions; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

Program: Tsaf_sysR_1-2.sas (Page 2 of 2)

Table 14.3.1-2.3-3: Frequency of subjects with solicited systemic reactions by grade - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Prime up to Day 7 after prime		nn	12	12	12	12	12	60
	Any	Any n (%)	9 (75)	9 (75)	12 (100)	9 (75)	9 (75)	48 (80)
		Mild n (%)	9 (75)	9 (75)	11 (92)	9 (75)	9 (75)	47 (78)
		Moderate n (%)	1 (8)	2 (17)	4 (33)	3 (25)	2 (17)	12 (20)
		Severe n (%)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
	Nausea	Any n (%)	1 (8)	0 (0)	5 (42)	0 (0)	2 (17)	8 (13)
		Mild n (%)	1 (8)	0 (0)	5 (42)	0 (0)	2 (17)	8 (13)
	Diarrhea	Any n (%)	1 (8)	1 (8)	0 (0)	2 (17)	2 (17)	6 (10)
		Mild n (%)	1 (8)	1 (8)	0 (0)	2 (17)	2 (17)	6 (10)
	Headache	Any n (%)	3 (25)	6 (50)	6 (50)	4 (33)	5 (42)	24 (40)
		Mild n (%)	3 (25)	5 (42)	4 (33)	2 (17)	5 (42)	19 (32)
		Moderate n (%)	0 (0)	2 (17)	3 (25)	2 (17)	0 (0)	7 (12)
		Severe n (%)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
	Fatigue	Any n (%)	6 (50)	6 (50)	6 (50)	8 (67)	5 (42)	31 (52)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_3-4.sas (Page 1 of 16)

Table 14.3.1-2.3-3: Frequency of subjects with solicited systemic reactions by grade - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Prime up to Day 7 after prime	Fatigue	Mild n (%)	6 (50)	6 (50)	5 (42)	8 (67)	4 (33)	29 (48)
		Moderate n (%)	0 (0)	0 (0)	1 (8)	1 (8)	2 (17)	4 (7)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Myalgia	Any n (%)	2 (17)	3 (25)	3 (25)	2 (17)	2 (17)	12 (20)
		Mild n (%)	2 (17)	3 (25)	3 (25)	1 (8)	2 (17)	11 (18)
		Moderate n (%)	1 (8)	0 (0)	0 (0)	2 (17)	1 (8)	4 (7)
	Arthralgia	Any n (%)	1 (8)	1 (8)	3 (25)	2 (17)	0 (0)	7 (12)
		Mild n (%)	1 (8)	1 (8)	3 (25)	1 (8)	0 (0)	6 (10)
		Moderate n (%)	1 (8)	0 (0)	0 (0)	2 (17)	0 (0)	3 (5)
	Chills	Any n (%)	1 (8)	0 (0)	1 (8)	0 (0)	1 (8)	3 (5)
		Mild n (%)	1 (8)	0 (0)	1 (8)	0 (0)	1 (8)	3 (5)
	Loss of Appetite	Any n (%)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (3)
		Mild n (%)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (3)
	Malaise	Any n (%)	4 (33)	5 (42)	1 (8)	1 (8)	4 (33)	15 (25)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_3-4.sas (Page 2 of 16)

Table 14.3.1-2.3-3: Frequency of subjects with solicited systemic reactions by grade - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Prime up to Day 7 after prime	Malaise	Mild n (%)	4 (33)	5 (42)	1 (8)	0 (0)	3 (25)	13 (22)
		Moderate n (%)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	3 (5)
Boost up to Day 7 after boost		nn	11	12	11	12	12	58
	Any	Any n (%)	4 (36)	2 (17)	7 (64)	10 (83)	10 (83)	33 (57)
		Mild n (%)	3 (27)	2 (17)	6 (55)	10 (83)	9 (75)	30 (52)
		Moderate n (%)	1 (9)	1 (8)	3 (27)	5 (42)	6 (50)	16 (28)
		Severe n (%)	0 (0)	0 (0)	1 (9)	1 (8)	3 (25)	5 (9)
	Nausea	Any n (%)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	3 (5)
		Mild n (%)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	2 (3)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
	Diarrhea	Any n (%)	1 (9)	1 (8)	1 (9)	1 (8)	0 (0)	4 (7)
		Mild n (%)	1 (9)	1 (8)	1 (9)	1 (8)	0 (0)	4 (7)
	Headache	Any n (%)	0 (0)	2 (17)	7 (64)	6 (50)	5 (42)	20 (34)
		Mild n (%)	0 (0)	2 (17)	4 (36)	6 (50)	4 (33)	16 (28)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_3-4.sas (Page 3 of 16)

Table 14.3.1-2.3-3: Frequency of subjects with solicited systemic reactions by grade - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Boost up to Day 7 after boost	Headache	Moderate n (%)	0 (0)	1 (8)	3 (27)	2 (17)	2 (17)	8 (14)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Fatigue	Any n (%)	4 (36)	1 (8)	5 (45)	4 (33)	8 (67)	22 (38)
		Mild n (%)	3 (27)	1 (8)	3 (27)	4 (33)	7 (58)	18 (31)
		Moderate n (%)	1 (9)	0 (0)	2 (18)	2 (17)	3 (25)	8 (14)
		Severe n (%)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	3 (5)
	Myalgia	Any n (%)	0 (0)	1 (8)	3 (27)	6 (50)	6 (50)	16 (28)
		Mild n (%)	0 (0)	1 (8)	2 (18)	4 (33)	5 (42)	12 (21)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	3 (25)	1 (8)	4 (7)
		Severe n (%)	0 (0)	0 (0)	1 (9)	0 (0)	2 (17)	3 (5)
	Arthralgia	Any n (%)	0 (0)	0 (0)	4 (36)	2 (17)	6 (50)	12 (21)
		Mild n (%)	0 (0)	0 (0)	2 (18)	1 (8)	5 (42)	8 (14)
		Moderate n (%)	0 (0)	0 (0)	2 (18)	2 (17)	1 (8)	5 (9)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	3 (5)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_3-4.sas (Page 4 of 16)

Table 14.3.1-2.3-3: Frequency of subjects with solicited systemic reactions by grade - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Boost up to Day 7 after boost	Chills	Any n (%)	0 (0)	0 (0)	2 (18)	4 (33)	6 (50)	12 (21)
		Mild n (%)	0 (0)	0 (0)	0 (0)	2 (17)	4 (33)	6 (10)
		Moderate n (%)	0 (0)	0 (0)	2 (18)	1 (8)	1 (8)	4 (7)
		Severe n (%)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)
	Loss of Appetite	Any n (%)	0 (0)	1 (8)	0 (0)	1 (8)	2 (17)	4 (7)
		Mild n (%)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	3 (5)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
	Malaise	Any n (%)	0 (0)	2 (17)	3 (27)	4 (33)	6 (50)	15 (26)
		Mild n (%)	0 (0)	2 (17)	1 (9)	3 (25)	4 (33)	10 (17)
		Moderate n (%)	0 (0)	0 (0)	1 (9)	1 (8)	5 (42)	7 (12)
		Severe n (%)	0 (0)	0 (0)	1 (9)	0 (0)	1 (8)	2 (3)
	Fever	Any n (%)	0 (0)	0 (0)	1 (9)	1 (8)	0 (0)	2 (3)
		Mild n (%)	0 (0)	0 (0)	1 (9)	1 (8)	0 (0)	2 (3)
Combined interval		nn	12	12	12	12	12	60

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_3-4.sas (Page 5 of 16)

Table 14.3.1-2.3-3: Frequency of subjects with solicited systemic reactions by grade - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Combined interval	Any	Any n (%)	9 (75)	9 (75)	12 (100)	11 (92)	12 (100)	53 (88)
		Mild n (%)	9 (75)	9 (75)	12 (100)	11 (92)	12 (100)	53 (88)
		Moderate n (%)	2 (17)	3 (25)	5 (42)	6 (50)	7 (58)	23 (38)
		Severe n (%)	0 (0)	0 (0)	1 (8)	2 (17)	3 (25)	6 (10)
	Nausea	Any n (%)	1 (8)	1 (8)	5 (42)	1 (8)	2 (17)	10 (17)
		Mild n (%)	1 (8)	1 (8)	5 (42)	1 (8)	2 (17)	10 (17)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
	Diarrhea	Any n (%)	2 (17)	2 (17)	1 (8)	2 (17)	2 (17)	9 (15)
		Mild n (%)	2 (17)	2 (17)	1 (8)	2 (17)	2 (17)	9 (15)
	Headache	Any n (%)	3 (25)	6 (50)	9 (75)	7 (58)	7 (58)	32 (53)
		Mild n (%)	3 (25)	5 (42)	7 (58)	7 (58)	6 (50)	28 (47)
		Moderate n (%)	0 (0)	3 (25)	4 (33)	3 (25)	2 (17)	12 (20)
		Severe n (%)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
	Fatigue	Any n (%)	7 (58)	7 (58)	8 (67)	9 (75)	9 (75)	40 (67)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_3-4.sas (Page 6 of 16)

Table 14.3.1-2.3-3: Frequency of subjects with solicited systemic reactions by grade - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Combined interval	Fatigue	Mild n (%)	7 (58)	7 (58)	6 (50)	9 (75)	8 (67)	37 (62)
		Moderate n (%)	1 (8)	0 (0)	3 (25)	3 (25)	4 (33)	11 (18)
		Severe n (%)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	3 (5)
	Myalgia	Any n (%)	2 (17)	3 (25)	5 (42)	6 (50)	7 (58)	23 (38)
		Mild n (%)	2 (17)	3 (25)	4 (33)	4 (33)	6 (50)	19 (32)
		Moderate n (%)	1 (8)	0 (0)	0 (0)	3 (25)	2 (17)	6 (10)
		Severe n (%)	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	3 (5)
	Arthralgia	Any n (%)	1 (8)	1 (8)	6 (50)	2 (17)	6 (50)	16 (27)
		Mild n (%)	1 (8)	1 (8)	4 (33)	1 (8)	5 (42)	12 (20)
		Moderate n (%)	1 (8)	0 (0)	2 (17)	2 (17)	1 (8)	6 (10)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	3 (5)
	Chills	Any n (%)	1 (8)	0 (0)	3 (25)	4 (33)	6 (50)	14 (23)
		Mild n (%)	1 (8)	0 (0)	1 (8)	2 (17)	5 (42)	9 (15)
		Moderate n (%)	0 (0)	0 (0)	2 (17)	1 (8)	1 (8)	4 (7)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.3-3: Frequency of subjects with solicited systemic reactions by grade - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Combined interval	Chills	Severe n (%)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)
	Loss of Appetite	Any n (%)	1 (8)	1 (8)	1 (8)	1 (8)	2 (17)	6 (10)
		Mild n (%)	1 (8)	1 (8)	1 (8)	1 (8)	1 (8)	5 (8)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
	Malaise	Any n (%)	4 (33)	5 (42)	4 (33)	4 (33)	7 (58)	24 (40)
		Mild n (%)	4 (33)	5 (42)	2 (17)	3 (25)	5 (42)	19 (32)
		Moderate n (%)	1 (8)	0 (0)	1 (8)	1 (8)	6 (50)	9 (15)
		Severe n (%)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Fever	Any n (%)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (3)
		Mild n (%)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (3)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_3-4.sas (Page 8 of 16)

Table 14.3.1-2.3-3: Frequency of subjects with solicited systemic reactions by grade - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Prime up to Day 7 after prime		nn	12	12	12	36	96
	Any	Any n (%)	3 (25)	4 (33)	9 (75)	16 (44)	64 (67)
		Mild n (%)	3 (25)	4 (33)	9 (75)	16 (44)	63 (66)
		Moderate n (%)	2 (17)	1 (8)	1 (8)	4 (11)	16 (17)
		Severe n (%)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
	Nausea	Any n (%)	2 (17)	0 (0)	1 (8)	3 (8)	11 (11)
		Mild n (%)	2 (17)	0 (0)	1 (8)	3 (8)	11 (11)
	Diarrhea	Any n (%)	1 (8)	0 (0)	1 (8)	2 (6)	8 (8)
		Mild n (%)	1 (8)	0 (0)	1 (8)	2 (6)	8 (8)
	Headache	Any n (%)	2 (17)	3 (25)	5 (42)	10 (28)	34 (35)
		Mild n (%)	2 (17)	2 (17)	4 (33)	8 (22)	27 (28)
		Moderate n (%)	1 (8)	1 (8)	1 (8)	3 (8)	10 (10)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Fatigue	Any n (%)	3 (25)	3 (25)	7 (58)	13 (36)	44 (46)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.3-3: Frequency of subjects with solicited systemic reactions by grade - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Prime up to Day 7 after prime	Fatigue	Mild n (%)	3 (25)	3 (25)	7 (58)	13 (36)	42 (44)
		Moderate n (%)	1 (8)	0 (0)	0 (0)	1 (3)	5 (5)
		Severe n (%)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Myalgia	Any n (%)	1 (8)	0 (0)	2 (17)	3 (8)	15 (16)
		Mild n (%)	0 (0)	0 (0)	2 (17)	2 (6)	13 (14)
		Moderate n (%)	1 (8)	0 (0)	0 (0)	1 (3)	5 (5)
	Arthralgia	Any n (%)	1 (8)	0 (0)	0 (0)	1 (3)	8 (8)
		Mild n (%)	1 (8)	0 (0)	0 (0)	1 (3)	7 (7)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Chills	Any n (%)	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
		Mild n (%)	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
	Loss of Appetite	Any n (%)	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
		Mild n (%)	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
	Malaise	Any n (%)	2 (17)	1 (8)	2 (17)	5 (14)	20 (21)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.3-3: Frequency of subjects with solicited systemic reactions by grade - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Prime up to Day 7 after prime	Malaise	Mild n (%)	2 (17)	1 (8)	2 (17)	5 (14)	18 (19)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Boost up to Day 7 after boost		nn	12	12	12	36	94
	Any	Any n (%)	4 (33)	8 (67)	11 (92)	23 (64)	56 (60)
		Mild n (%)	3 (25)	8 (67)	11 (92)	22 (61)	52 (55)
		Moderate n (%)	2 (17)	2 (17)	7 (58)	11 (31)	27 (29)
		Severe n (%)	1 (8)	0 (0)	2 (17)	3 (8)	8 (9)
	Nausea	Any n (%)	2 (17)	0 (0)	2 (17)	4 (11)	7 (7)
		Mild n (%)	1 (8)	0 (0)	2 (17)	3 (8)	5 (5)
		Severe n (%)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
	Diarrhea	Any n (%)	0 (0)	0 (0)	1 (8)	1 (3)	5 (5)
		Mild n (%)	0 (0)	0 (0)	1 (8)	1 (3)	5 (5)
	Headache	Any n (%)	2 (17)	5 (42)	8 (67)	15 (42)	35 (37)
		Mild n (%)	1 (8)	5 (42)	7 (58)	13 (36)	29 (31)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.3-3: Frequency of subjects with solicited systemic reactions by grade - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Boost up to Day 7 after boost	Headache	Moderate n (%)	2 (17)	1 (8)	3 (25)	6 (17)	14 (15)
		Severe n (%)	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
	Fatigue	Any n (%)	3 (25)	6 (50)	7 (58)	16 (44)	38 (40)
		Mild n (%)	2 (17)	6 (50)	5 (42)	13 (36)	31 (33)
		Moderate n (%)	2 (17)	2 (17)	3 (25)	7 (19)	15 (16)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Myalgia	Any n (%)	2 (17)	4 (33)	4 (33)	10 (28)	26 (28)
		Mild n (%)	1 (8)	4 (33)	3 (25)	8 (22)	20 (21)
		Moderate n (%)	1 (8)	1 (8)	1 (8)	3 (8)	7 (7)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Arthralgia	Any n (%)	0 (0)	1 (8)	3 (25)	4 (11)	16 (17)
		Mild n (%)	0 (0)	1 (8)	3 (25)	4 (11)	12 (13)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.3-3: Frequency of subjects with solicited systemic reactions by grade - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Boost up to Day 7 after boost	Chills	Any n (%)	0 (0)	1 (8)	4 (33)	5 (14)	17 (18)
		Mild n (%)	0 (0)	1 (8)	2 (17)	3 (8)	9 (10)
		Moderate n (%)	0 (0)	0 (0)	2 (17)	2 (6)	6 (6)
		Severe n (%)	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
	Loss of Appetite	Any n (%)	1 (8)	1 (8)	3 (25)	5 (14)	9 (10)
		Mild n (%)	0 (0)	1 (8)	3 (25)	4 (11)	7 (7)
		Moderate n (%)	1 (8)	0 (0)	1 (8)	2 (6)	3 (3)
	Malaise	Any n (%)	2 (17)	1 (8)	5 (42)	8 (22)	23 (24)
		Mild n (%)	0 (0)	1 (8)	3 (25)	4 (11)	14 (15)
		Moderate n (%)	1 (8)	0 (0)	3 (25)	4 (11)	11 (12)
		Severe n (%)	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
	Fever	Any n (%)	0 (0)	0 (0)	3 (25)	3 (8)	5 (5)
		Mild n (%)	0 (0)	0 (0)	3 (25)	3 (8)	5 (5)
Combined interval		nn	12	12	12	36	96

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.3-3: Frequency of subjects with solicited systemic reactions by grade - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Combined interval	Any	Any n (%)	5 (42)	10 (83)	11 (92)	26 (72)	79 (82)
		Mild n (%)	4 (33)	10 (83)	11 (92)	25 (69)	78 (81)
		Moderate n (%)	3 (25)	3 (25)	7 (58)	13 (36)	36 (38)
		Severe n (%)	2 (17)	0 (0)	2 (17)	4 (11)	10 (10)
	Nausea	Any n (%)	3 (25)	0 (0)	3 (25)	6 (17)	16 (17)
		Mild n (%)	2 (17)	0 (0)	3 (25)	5 (14)	15 (16)
		Severe n (%)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
	Diarrhea	Any n (%)	1 (8)	0 (0)	2 (17)	3 (8)	12 (13)
		Mild n (%)	1 (8)	0 (0)	2 (17)	3 (8)	12 (13)
	Headache	Any n (%)	3 (25)	6 (50)	8 (67)	17 (47)	49 (51)
		Mild n (%)	2 (17)	6 (50)	7 (58)	15 (42)	43 (45)
		Moderate n (%)	2 (17)	2 (17)	3 (25)	7 (19)	19 (20)
		Severe n (%)	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
	Fatigue	Any n (%)	4 (33)	7 (58)	9 (75)	20 (56)	60 (63)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.3-3: Frequency of subjects with solicited systemic reactions by grade - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Combined interval	Fatigue	Mild n (%)	3 (25)	7 (58)	8 (67)	18 (50)	55 (57)
		Moderate n (%)	3 (25)	2 (17)	3 (25)	8 (22)	19 (20)
		Severe n (%)	1 (8)	0 (0)	0 (0)	1 (3)	4 (4)
	Myalgia	Any n (%)	3 (25)	4 (33)	5 (42)	12 (33)	35 (36)
		Mild n (%)	1 (8)	4 (33)	5 (42)	10 (28)	29 (30)
		Moderate n (%)	2 (17)	1 (8)	1 (8)	4 (11)	10 (10)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Arthralgia	Any n (%)	1 (8)	1 (8)	3 (25)	5 (14)	21 (22)
		Mild n (%)	1 (8)	1 (8)	3 (25)	5 (14)	17 (18)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Chills	Any n (%)	0 (0)	1 (8)	4 (33)	5 (14)	19 (20)
		Mild n (%)	0 (0)	1 (8)	3 (25)	4 (11)	13 (14)
		Moderate n (%)	0 (0)	0 (0)	2 (17)	2 (6)	6 (6)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

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Table 14.3.1-2.3-3: Frequency of subjects with solicited systemic reactions by grade - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Combined interval	Chills	Severe n (%)	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
	Loss of Appetite	Any n (%)	2 (17)	1 (8)	3 (25)	6 (17)	12 (13)
		Mild n (%)	1 (8)	1 (8)	3 (25)	5 (14)	10 (10)
		Moderate n (%)	1 (8)	0 (0)	1 (8)	2 (6)	3 (3)
	Malaise	Any n (%)	3 (25)	2 (17)	7 (58)	12 (33)	36 (38)
		Mild n (%)	2 (17)	2 (17)	5 (42)	9 (25)	28 (29)
		Moderate n (%)	1 (8)	0 (0)	3 (25)	4 (11)	13 (14)
		Severe n (%)	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
	Fever	Any n (%)	0 (0)	0 (0)	3 (25)	3 (8)	5 (5)
		Mild n (%)	0 (0)	0 (0)	3 (25)	3 (8)	5 (5)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_3-4.sas (Page 16 of 16)

Table 14.3.1-2.4-3: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Prime up to Day 7 after prime		nn	12	12	12	12	12	60
	Any	Any n (%)	9 (75)	9 (75)	12 (100)	9 (75)	9 (75)	48 (80)
		Mild n (%)	9 (75)	9 (75)	11 (92)	9 (75)	9 (75)	47 (78)
		Moderate n (%)	1 (8)	2 (17)	4 (33)	3 (25)	2 (17)	12 (20)
		Severe n (%)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
	Nausea	Any n (%)	1 (8)	0 (0)	5 (42)	0 (0)	2 (17)	8 (13)
		Mild n (%)	1 (8)	0 (0)	5 (42)	0 (0)	2 (17)	8 (13)
	Diarrhea	Any n (%)	1 (8)	1 (8)	0 (0)	2 (17)	2 (17)	6 (10)
		Mild n (%)	1 (8)	1 (8)	0 (0)	2 (17)	2 (17)	6 (10)
	Headache	Any n (%)	3 (25)	6 (50)	6 (50)	4 (33)	5 (42)	24 (40)
		Mild n (%)	3 (25)	5 (42)	4 (33)	2 (17)	5 (42)	19 (32)
		Moderate n (%)	0 (0)	2 (17)	3 (25)	2 (17)	0 (0)	7 (12)
		Severe n (%)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
	Fatigue	Any n (%)	6 (50)	6 (50)	6 (50)	8 (67)	5 (42)	31 (52)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-3: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Prime up to Day 7 after prime	Fatigue	Mild n (%)	6 (50)	6 (50)	5 (42)	8 (67)	4 (33)	29 (48)
		Moderate n (%)	0 (0)	0 (0)	1 (8)	1 (8)	2 (17)	4 (7)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Myalgia	Any n (%)	2 (17)	3 (25)	3 (25)	2 (17)	2 (17)	12 (20)
		Mild n (%)	2 (17)	3 (25)	3 (25)	1 (8)	2 (17)	11 (18)
		Moderate n (%)	1 (8)	0 (0)	0 (0)	2 (17)	1 (8)	4 (7)
	Arthralgia	Any n (%)	1 (8)	1 (8)	3 (25)	2 (17)	0 (0)	7 (12)
		Mild n (%)	1 (8)	1 (8)	3 (25)	1 (8)	0 (0)	6 (10)
		Moderate n (%)	1 (8)	0 (0)	0 (0)	2 (17)	0 (0)	3 (5)
	Chills	Any n (%)	1 (8)	0 (0)	1 (8)	0 (0)	1 (8)	3 (5)
		Mild n (%)	1 (8)	0 (0)	1 (8)	0 (0)	1 (8)	3 (5)
	Loss of Appetite	Any n (%)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (3)
		Mild n (%)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (3)
	Malaise	Any n (%)	4 (33)	5 (42)	1 (8)	1 (8)	4 (33)	15 (25)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

Program: Tsaf_sysR_3-4.sas (Page 2 of 16)

Table 14.3.1-2.4-3: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Prime up to Day 7 after prime	Malaise	Mild n (%)	4 (33)	5 (42)	1 (8)	0 (0)	3 (25)	13 (22)
		Moderate n (%)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	3 (5)
Boost up to Day 7 after boost		nn	11	12	11	12	12	58
	Any	Any n (%)	4 (36)	2 (17)	7 (64)	10 (83)	10 (83)	33 (57)
		Mild n (%)	3 (27)	2 (17)	6 (55)	10 (83)	9 (75)	30 (52)
		Moderate n (%)	1 (9)	1 (8)	3 (27)	5 (42)	6 (50)	16 (28)
		Severe n (%)	0 (0)	0 (0)	1 (9)	1 (8)	3 (25)	5 (9)
	Nausea	Any n (%)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	3 (5)
		Mild n (%)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	2 (3)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
	Diarrhea	Any n (%)	1 (9)	1 (8)	1 (9)	1 (8)	0 (0)	4 (7)
		Mild n (%)	1 (9)	1 (8)	1 (9)	1 (8)	0 (0)	4 (7)
	Headache	Any n (%)	0 (0)	2 (17)	7 (64)	6 (50)	5 (42)	20 (34)
		Mild n (%)	0 (0)	2 (17)	4 (36)	6 (50)	4 (33)	16 (28)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-3: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Boost up to Day 7 after boost	Headache	Moderate n (%)	0 (0)	1 (8)	3 (27)	2 (17)	2 (17)	8 (14)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Fatigue	Any n (%)	4 (36)	1 (8)	5 (45)	4 (33)	8 (67)	22 (38)
		Mild n (%)	3 (27)	1 (8)	3 (27)	4 (33)	7 (58)	18 (31)
		Moderate n (%)	1 (9)	0 (0)	2 (18)	2 (17)	3 (25)	8 (14)
		Severe n (%)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	3 (5)
	Myalgia	Any n (%)	0 (0)	1 (8)	3 (27)	6 (50)	6 (50)	16 (28)
		Mild n (%)	0 (0)	1 (8)	2 (18)	4 (33)	5 (42)	12 (21)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	3 (25)	1 (8)	4 (7)
		Severe n (%)	0 (0)	0 (0)	1 (9)	0 (0)	2 (17)	3 (5)
	Arthralgia	Any n (%)	0 (0)	0 (0)	4 (36)	2 (17)	6 (50)	12 (21)
		Mild n (%)	0 (0)	0 (0)	2 (18)	1 (8)	5 (42)	8 (14)
		Moderate n (%)	0 (0)	0 (0)	2 (18)	2 (17)	1 (8)	5 (9)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	3 (5)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-3: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Boost up to Day 7 after boost	Chills	Any n (%)	0 (0)	0 (0)	2 (18)	4 (33)	6 (50)	12 (21)
		Mild n (%)	0 (0)	0 (0)	0 (0)	2 (17)	4 (33)	6 (10)
		Moderate n (%)	0 (0)	0 (0)	2 (18)	1 (8)	1 (8)	4 (7)
		Severe n (%)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)
	Loss of Appetite	Any n (%)	0 (0)	1 (8)	0 (0)	1 (8)	2 (17)	4 (7)
		Mild n (%)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	3 (5)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
	Malaise	Any n (%)	0 (0)	2 (17)	3 (27)	4 (33)	6 (50)	15 (26)
		Mild n (%)	0 (0)	2 (17)	1 (9)	3 (25)	4 (33)	10 (17)
		Moderate n (%)	0 (0)	0 (0)	1 (9)	1 (8)	5 (42)	7 (12)
		Severe n (%)	0 (0)	0 (0)	1 (9)	0 (0)	1 (8)	2 (3)
	Fever	Any n (%)	0 (0)	0 (0)	1 (9)	1 (8)	0 (0)	2 (3)
		Mild n (%)	0 (0)	0 (0)	1 (9)	1 (8)	0 (0)	2 (3)
Combined interval		nn	11	12	11	12	12	58

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-3: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Combined interval	Any	Any n (%)	8 (73)	9 (75)	11 (100)	11 (92)	12 (100)	51 (88)
		Mild n (%)	8 (73)	9 (75)	11 (100)	11 (92)	12 (100)	51 (88)
		Moderate n (%)	1 (9)	3 (25)	5 (45)	6 (50)	7 (58)	22 (38)
		Severe n (%)	0 (0)	0 (0)	1 (9)	2 (17)	3 (25)	6 (10)
	Nausea	Any n (%)	0 (0)	1 (8)	4 (36)	1 (8)	2 (17)	8 (14)
		Mild n (%)	0 (0)	1 (8)	4 (36)	1 (8)	2 (17)	8 (14)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
	Diarrhea	Any n (%)	1 (9)	2 (17)	1 (9)	2 (17)	2 (17)	8 (14)
		Mild n (%)	1 (9)	2 (17)	1 (9)	2 (17)	2 (17)	8 (14)
	Headache	Any n (%)	2 (18)	6 (50)	8 (73)	7 (58)	7 (58)	30 (52)
		Mild n (%)	2 (18)	5 (42)	6 (55)	7 (58)	6 (50)	26 (45)
		Moderate n (%)	0 (0)	3 (25)	4 (36)	3 (25)	2 (17)	12 (21)
		Severe n (%)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
	Fatigue	Any n (%)	6 (55)	7 (58)	8 (73)	9 (75)	9 (75)	39 (67)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-3: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Combined interval	Fatigue	Mild n (%)	6 (55)	7 (58)	6 (55)	9 (75)	8 (67)	36 (62)
		Moderate n (%)	1 (9)	0 (0)	3 (27)	3 (25)	4 (33)	11 (19)
		Severe n (%)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	3 (5)
	Myalgia	Any n (%)	1 (9)	3 (25)	5 (45)	6 (50)	7 (58)	22 (38)
		Mild n (%)	1 (9)	3 (25)	4 (36)	4 (33)	6 (50)	18 (31)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	3 (25)	2 (17)	5 (9)
		Severe n (%)	0 (0)	0 (0)	1 (9)	0 (0)	2 (17)	3 (5)
	Arthralgia	Any n (%)	0 (0)	1 (8)	6 (55)	2 (17)	6 (50)	15 (26)
		Mild n (%)	0 (0)	1 (8)	4 (36)	1 (8)	5 (42)	11 (19)
		Moderate n (%)	0 (0)	0 (0)	2 (18)	2 (17)	1 (8)	5 (9)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (25)	3 (5)
	Chills	Any n (%)	0 (0)	0 (0)	3 (27)	4 (33)	6 (50)	13 (22)
		Mild n (%)	0 (0)	0 (0)	1 (9)	2 (17)	5 (42)	8 (14)
		Moderate n (%)	0 (0)	0 (0)	2 (18)	1 (8)	1 (8)	4 (7)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-3: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b2

Safety set

			Younger dose ranging cohorts					
Time interval			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Combined interval	Chills	Severe n (%)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)
	Loss of Appetite	Any n (%)	1 (9)	1 (8)	1 (9)	1 (8)	2 (17)	6 (10)
		Mild n (%)	1 (9)	1 (8)	1 (9)	1 (8)	1 (8)	5 (9)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
	Malaise	Any n (%)	3 (27)	5 (42)	4 (36)	4 (33)	7 (58)	23 (40)
		Mild n (%)	3 (27)	5 (42)	2 (18)	3 (25)	5 (42)	18 (31)
		Moderate n (%)	0 (0)	0 (0)	1 (9)	1 (8)	6 (50)	8 (14)
		Severe n (%)	0 (0)	0 (0)	1 (9)	0 (0)	1 (8)	2 (3)
	Fever	Any n (%)	0 (0)	0 (0)	1 (9)	1 (8)	0 (0)	2 (3)
		Mild n (%)	0 (0)	0 (0)	1 (9)	1 (8)	0 (0)	2 (3)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-3: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Prime up to Day 7 after prime		nn	12	12	12	36	96
	Any	Any n (%)	3 (25)	4 (33)	9 (75)	16 (44)	64 (67)
		Mild n (%)	3 (25)	4 (33)	9 (75)	16 (44)	63 (66)
		Moderate n (%)	2 (17)	1 (8)	1 (8)	4 (11)	16 (17)
		Severe n (%)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
	Nausea	Any n (%)	2 (17)	0 (0)	1 (8)	3 (8)	11 (11)
		Mild n (%)	2 (17)	0 (0)	1 (8)	3 (8)	11 (11)
	Diarrhea	Any n (%)	1 (8)	0 (0)	1 (8)	2 (6)	8 (8)
		Mild n (%)	1 (8)	0 (0)	1 (8)	2 (6)	8 (8)
	Headache	Any n (%)	2 (17)	3 (25)	5 (42)	10 (28)	34 (35)
		Mild n (%)	2 (17)	2 (17)	4 (33)	8 (22)	27 (28)
		Moderate n (%)	1 (8)	1 (8)	1 (8)	3 (8)	10 (10)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Fatigue	Any n (%)	3 (25)	3 (25)	7 (58)	13 (36)	44 (46)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-3: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Prime up to Day 7 after prime	Fatigue	Mild n (%)	3 (25)	3 (25)	7 (58)	13 (36)	42 (44)
		Moderate n (%)	1 (8)	0 (0)	0 (0)	1 (3)	5 (5)
		Severe n (%)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Myalgia	Any n (%)	1 (8)	0 (0)	2 (17)	3 (8)	15 (16)
		Mild n (%)	0 (0)	0 (0)	2 (17)	2 (6)	13 (14)
		Moderate n (%)	1 (8)	0 (0)	0 (0)	1 (3)	5 (5)
	Arthralgia	Any n (%)	1 (8)	0 (0)	0 (0)	1 (3)	8 (8)
		Mild n (%)	1 (8)	0 (0)	0 (0)	1 (3)	7 (7)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Chills	Any n (%)	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
		Mild n (%)	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
	Loss of Appetite	Any n (%)	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
		Mild n (%)	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
	Malaise	Any n (%)	2 (17)	1 (8)	2 (17)	5 (14)	20 (21)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-3: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Prime up to Day 7 after prime	Malaise	Mild n (%)	2 (17)	1 (8)	2 (17)	5 (14)	18 (19)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Boost up to Day 7 after boost		nn	12	12	12	36	94
	Any	Any n (%)	4 (33)	8 (67)	11 (92)	23 (64)	56 (60)
		Mild n (%)	3 (25)	8 (67)	11 (92)	22 (61)	52 (55)
		Moderate n (%)	2 (17)	2 (17)	7 (58)	11 (31)	27 (29)
		Severe n (%)	1 (8)	0 (0)	2 (17)	3 (8)	8 (9)
	Nausea	Any n (%)	2 (17)	0 (0)	2 (17)	4 (11)	7 (7)
		Mild n (%)	1 (8)	0 (0)	2 (17)	3 (8)	5 (5)
		Severe n (%)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
	Diarrhea	Any n (%)	0 (0)	0 (0)	1 (8)	1 (3)	5 (5)
		Mild n (%)	0 (0)	0 (0)	1 (8)	1 (3)	5 (5)
	Headache	Any n (%)	2 (17)	5 (42)	8 (67)	15 (42)	35 (37)
		Mild n (%)	1 (8)	5 (42)	7 (58)	13 (36)	29 (31)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-3: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Boost up to Day 7 after boost	Headache	Moderate n (%)	2 (17)	1 (8)	3 (25)	6 (17)	14 (15)
		Severe n (%)	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
	Fatigue	Any n (%)	3 (25)	6 (50)	7 (58)	16 (44)	38 (40)
		Mild n (%)	2 (17)	6 (50)	5 (42)	13 (36)	31 (33)
		Moderate n (%)	2 (17)	2 (17)	3 (25)	7 (19)	15 (16)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Myalgia	Any n (%)	2 (17)	4 (33)	4 (33)	10 (28)	26 (28)
		Mild n (%)	1 (8)	4 (33)	3 (25)	8 (22)	20 (21)
		Moderate n (%)	1 (8)	1 (8)	1 (8)	3 (8)	7 (7)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Arthralgia	Any n (%)	0 (0)	1 (8)	3 (25)	4 (11)	16 (17)
		Mild n (%)	0 (0)	1 (8)	3 (25)	4 (11)	12 (13)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-3: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Boost up to Day 7 after boost	Chills	Any n (%)	0 (0)	1 (8)	4 (33)	5 (14)	17 (18)
		Mild n (%)	0 (0)	1 (8)	2 (17)	3 (8)	9 (10)
		Moderate n (%)	0 (0)	0 (0)	2 (17)	2 (6)	6 (6)
		Severe n (%)	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
	Loss of Appetite	Any n (%)	1 (8)	1 (8)	3 (25)	5 (14)	9 (10)
		Mild n (%)	0 (0)	1 (8)	3 (25)	4 (11)	7 (7)
		Moderate n (%)	1 (8)	0 (0)	1 (8)	2 (6)	3 (3)
	Malaise	Any n (%)	2 (17)	1 (8)	5 (42)	8 (22)	23 (24)
		Mild n (%)	0 (0)	1 (8)	3 (25)	4 (11)	14 (15)
		Moderate n (%)	1 (8)	0 (0)	3 (25)	4 (11)	11 (12)
		Severe n (%)	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
	Fever	Any n (%)	0 (0)	0 (0)	3 (25)	3 (8)	5 (5)
		Mild n (%)	0 (0)	0 (0)	3 (25)	3 (8)	5 (5)
Combined interval		nn	12	12	12	36	94

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-3: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Combined interval	Any	Any n (%)	5 (42)	10 (83)	11 (92)	26 (72)	77 (82)
		Mild n (%)	4 (33)	10 (83)	11 (92)	25 (69)	76 (81)
		Moderate n (%)	3 (25)	3 (25)	7 (58)	13 (36)	35 (37)
		Severe n (%)	2 (17)	0 (0)	2 (17)	4 (11)	10 (11)
	Nausea	Any n (%)	3 (25)	0 (0)	3 (25)	6 (17)	14 (15)
		Mild n (%)	2 (17)	0 (0)	3 (25)	5 (14)	13 (14)
		Severe n (%)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
	Diarrhea	Any n (%)	1 (8)	0 (0)	2 (17)	3 (8)	11 (12)
		Mild n (%)	1 (8)	0 (0)	2 (17)	3 (8)	11 (12)
	Headache	Any n (%)	3 (25)	6 (50)	8 (67)	17 (47)	47 (50)
		Mild n (%)	2 (17)	6 (50)	7 (58)	15 (42)	41 (44)
		Moderate n (%)	2 (17)	2 (17)	3 (25)	7 (19)	19 (20)
		Severe n (%)	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
	Fatigue	Any n (%)	4 (33)	7 (58)	9 (75)	20 (56)	59 (63)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-3: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Combined interval	Fatigue	Mild n (%)	3 (25)	7 (58)	8 (67)	18 (50)	54 (57)
		Moderate n (%)	3 (25)	2 (17)	3 (25)	8 (22)	19 (20)
		Severe n (%)	1 (8)	0 (0)	0 (0)	1 (3)	4 (4)
	Myalgia	Any n (%)	3 (25)	4 (33)	5 (42)	12 (33)	34 (36)
		Mild n (%)	1 (8)	4 (33)	5 (42)	10 (28)	28 (30)
		Moderate n (%)	2 (17)	1 (8)	1 (8)	4 (11)	9 (10)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Arthralgia	Any n (%)	1 (8)	1 (8)	3 (25)	5 (14)	20 (21)
		Mild n (%)	1 (8)	1 (8)	3 (25)	5 (14)	16 (17)
		Moderate n (%)	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
		Severe n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Chills	Any n (%)	0 (0)	1 (8)	4 (33)	5 (14)	18 (19)
		Mild n (%)	0 (0)	1 (8)	3 (25)	4 (11)	12 (13)
		Moderate n (%)	0 (0)	0 (0)	2 (17)	2 (6)	6 (6)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.4-3: Frequency of subjects with solicited systemic reactions by grade - completers only - BNT162b2

Safety set

			Older dose ranging cohorts				
Time interval			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Combined interval	Chills	Severe n (%)	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
	Loss of Appetite	Any n (%)	2 (17)	1 (8)	3 (25)	6 (17)	12 (13)
		Mild n (%)	1 (8)	1 (8)	3 (25)	5 (14)	10 (11)
		Moderate n (%)	1 (8)	0 (0)	1 (8)	2 (6)	3 (3)
	Malaise	Any n (%)	3 (25)	2 (17)	7 (58)	12 (33)	35 (37)
		Mild n (%)	2 (17)	2 (17)	5 (42)	9 (25)	27 (29)
		Moderate n (%)	1 (8)	0 (0)	3 (25)	4 (11)	12 (13)
		Severe n (%)	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
	Fever	Any n (%)	0 (0)	0 (0)	3 (25)	3 (8)	5 (5)
		Mild n (%)	0 (0)	0 (0)	3 (25)	3 (8)	5 (5)

The combined interval is the union of the intervals 'Prime up to Day 7 after prime' and 'Boost up to Day 7 after boost'. The denominator for the percentage calculation is nn.
N = number of subjects in the analysis set; n = number of subjects with the respective systemic reaction; nn = number of subjects with any information on systemic reactions available and which completed the respective time interval; N/A = not available; - = not estimable.

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Table 14.3.1-2.5.1-3: Descriptive statistics of time of solicited systemic reactions - BNT162b2

Safety set

			Younger dose ranging cohorts					
			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Time from dose to first systemic reaction [Days]	n	9	9	12	9	9	48
		Mean (SD)	1.7 (1.1)	1.2 (0.4)	1.5 (0.8)	1.7 (1.3)	3.1 (2.8)	1.8 (1.6)
		Min	1	1	1	1	1	1
		Median	1.0	1.0	1.0	1.0	2.0	1.0
		Max	4	2	3	5	8	8
	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	1	0	1
		Mean (SD)	- (-)	- (-)	- (-)	2.0 (-)	- (-)	2.0 (-)
		Min	-	-	-	2	-	2
		Median	-	-	-	2.0	-	2.0
		Max	-	-	-	2	-	2
	Time from first systemic reaction to last systemic reaction [Days]	n	9	9	12	9	9	48
		Mean (SD)	2.1 (2.7)	3.1 (2.2)	2.1 (1.6)	3.7 (2.1)	2.1 (1.7)	2.6 (2.1)
		Min	1	1	1	1	1	1
		Median	1.0	2.0	1.0	4.0	1.0	1.5
		Max	9	7	6	7	6	9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.1-3: Descriptive statistics of time of solicited systemic reactions - BNT162b2

Safety set

			Younger dose ranging cohorts					
			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	1	0	1
		Mean (SD)	- (-)	- (-)	- (-)	1.0 (-)	- (-)	1.0 (-)
		Min	-	-	-	1	-	1
		Median	-	-	-	1.0	-	1.0
		Max	-	-	-	1	-	1
After boost	Time from dose to first systemic reaction [Days]	n	4	2	7	10	10	33
		Mean (SD)	1.0 (0.0)	1.0 (-)	1.1 (0.4)	1.4 (0.5)	1.5 (0.5)	1.3 (0.5)
		Min	1	1	1	1	1	1
		Median	1.0	1.0	1.0	1.0	1.5	1.0
		Max	1	1	2	2	2	2
	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	1	1	3	5
		Mean (SD)	- (-)	- (-)	1.0 (-)	2.0 (-)	2.7 (1.2)	2.2 (1.1)
		Min	-	-	1	2	2	1
		Median	-	-	1.0	2.0	2.0	2.0
		Max	-	-	1	2	4	4

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.1-3: Descriptive statistics of time of solicited systemic reactions - BNT162b2

Safety set

			Younger dose ranging cohorts					
			1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Time from first systemic reaction to last systemic reaction [Days]	n	4	2	7	10	10	33
		Mean (SD)	2.5 (3.0)	8.5 (-)	2.0 (1.0)	2.6 (1.6)	2.2 (1.5)	2.7 (2.2)
		Min	1	8	1	1	1	1
		Median	1.0	8.5	2.0	2.0	2.0	2.0
		Max	7	9	3	6	6	9
	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	1	1	3	5
		Mean (SD)	- (-)	- (-)	1.0 (-)	1.0 (-)	1.3 (0.6)	1.2 (0.4)
		Min	-	-	1	1	1	1
		Median	-	-	1.0	1.0	1.0	1.0
		Max	-	-	1	1	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.1-3: Descriptive statistics of time of solicited systemic reactions - BNT162b2

Safety set

			Older dose ranging cohorts				
			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Time from dose to first systemic reaction [Days]	n	3	4	9	16	64
		Mean (SD)	1.0 (0.0)	1.5 (0.6)	1.8 (1.1)	1.6 (0.9)	1.8 (1.4)
		Min	1	1	1	1	1
		Median	1.0	1.5	1.0	1.0	1.0
		Max	1	2	4	4	8
	Time from dose to first systemic reaction with grade >= 3 [Days]	n	1	0	0	1	2
		Mean (SD)	1.0 (-)	- (-)	- (-)	1.0 (-)	1.5 (-)
		Min	1	-	-	1	1
		Median	1.0	-	-	1.0	1.5
		Max	1	-	-	1	2
	Time from first systemic reaction to last systemic reaction [Days]	n	3	4	9	16	64
		Mean (SD)	6.7 (0.6)	1.8 (0.5)	2.1 (2.0)	2.9 (2.4)	2.7 (2.1)
		Min	6	1	1	1	1
		Median	7.0	2.0	1.0	2.0	2.0
		Max	7	2	7	7	9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.1-3: Descriptive statistics of time of solicited systemic reactions - BNT162b2

Safety set

			Older dose ranging cohorts				
			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	1	0	0	1	2
		Mean (SD)	1.0 (-)	- (-)	- (-)	1.0 (-)	1.0 (-)
		Min	1	-	-	1	1
		Median	1.0	-	-	1.0	1.0
		Max	1	-	-	1	1
After boost	Time from dose to first systemic reaction [Days]	n	4	8	11	23	56
		Mean (SD)	1.0 (0.0)	2.0 (2.1)	1.3 (0.5)	1.5 (1.3)	1.4 (0.9)
		Min	1	1	1	1	1
		Median	1.0	1.0	1.0	1.0	1.0
		Max	1	7	2	7	7
	Time from dose to first systemic reaction with grade >= 3 [Days]	n	1	0	2	3	8
		Mean (SD)	1.0 (-)	- (-)	1.5 (-)	1.3 (0.6)	1.9 (1.0)
		Min	1	-	1	1	1
		Median	1.0	-	1.5	1.0	2.0
		Max	1	-	2	2	4

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.1-3: Descriptive statistics of time of solicited systemic reactions - BNT162b2

Safety set

			Older dose ranging cohorts				
			10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After boost	Time from first systemic reaction to last systemic reaction [Days]	n	4	8	11	23	56
		Mean (SD)	3.0 (2.8)	2.0 (1.1)	2.0 (1.2)	2.2 (1.5)	2.5 (1.9)
		Min	1	1	1	1	1
		Median	2.0	2.0	2.0	2.0	2.0
		Max	7	4	5	7	9
	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	1	0	2	3	8
		Mean (SD)	1.0 (-)	- (-)	1.5 (-)	1.3 (0.6)	1.3 (0.5)
		Min	1	-	1	1	1
		Median	1.0	-	1.5	1.0	1.0
		Max	1	-	2	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Nausea	Time from dose to first systemic reaction [Days]	n	1	0	5	0	2	8
			Mean (SD)	3.0 (-)	- (-)	2.4 (2.2)	- (-)	1.5 (-)	2.3 (1.8)
			Min	3	-	1	-	1	1
			Median	3.0	-	1.0	-	1.5	1.5
			Max	3	-	6	-	2	6
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
		Time from first systemic reaction to last systemic reaction [Days]	n	1	0	5	0	2	8
			Mean (SD)	1.0 (-)	- (-)	1.0 (0.0)	- (-)	2.0 (-)	1.3 (0.7)
			Min	1	-	1	-	1	1
			Median	1.0	-	1.0	-	2.0	1.0
			Max	1	-	1	-	3	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Nausea	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
	Vomiting	Time from dose to first systemic reaction [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Vomiting	Time from first systemic reaction to last systemic reaction [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
	Diarrhea	Time from dose to first systemic reaction [Days]	n	1	1	0	2	2	6
			Mean (SD)	3.0 (-)	2.0 (-)	- (-)	4.0 (-)	6.5 (-)	4.3 (2.2)
			Min	3	2	-	3	5	2
			Median	3.0	2.0	-	4.0	6.5	4.0
			Max	3	2	-	5	8	8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Diarrhea	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
		Time from first systemic reaction to last systemic reaction [Days]	n	1	1	0	2	2	6
			Mean (SD)	1.0 (-)	1.0 (-)	- (-)	1.5 (-)	1.0 (-)	1.2 (0.4)
			Min	1	1	-	1	1	1
			Median	1.0	1.0	-	1.5	1.0	1.0
			Max	1	1	-	2	1	2
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Headache	Time from dose to first systemic reaction [Days]	n	3	6	6	4	5	24
			Mean (SD)	1.3 (0.6)	1.7 (0.8)	2.2 (1.3)	2.0 (0.8)	2.6 (2.5)	2.0 (1.4)
			Min	1	1	1	1	1	1
			Median	1.0	1.5	2.0	2.0	2.0	2.0
			Max	2	3	4	3	7	7
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	1	0	1
			Mean (SD)	- (-)	- (-)	- (-)	2.0 (-)	- (-)	2.0 (-)
			Min	-	-	-	2	-	2
			Median	-	-	-	2.0	-	2.0
			Max	-	-	-	2	-	2
		Time from first systemic reaction to last systemic reaction [Days]	n	3	6	6	4	5	24
			Mean (SD)	3.3 (4.0)	2.8 (2.6)	1.2 (0.4)	3.3 (2.6)	1.4 (0.9)	2.3 (2.2)
			Min	1	1	1	1	1	1
			Median	1.0	1.5	1.0	3.0	1.0	1.0
			Max	8	7	2	6	3	8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Headache	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	1	0	1
			Mean (SD)	- (-)	- (-)	- (-)	1.0 (-)	- (-)	1.0 (-)
			Min	-	-	-	1	-	1
			Median	-	-	-	1.0	-	1.0
			Max	-	-	-	1	-	1
	Fatigue	Time from dose to first systemic reaction [Days]	n	6	6	6	8	5	31
			Mean (SD)	1.5 (1.2)	2.0 (2.0)	1.7 (0.8)	1.6 (1.4)	2.4 (2.6)	1.8 (1.6)
			Min	1	1	1	1	1	1
			Median	1.0	1.0	1.5	1.0	1.0	1.0
			Max	4	6	3	5	7	7
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Fatigue	Time from first systemic reaction to last systemic reaction [Days]	n	6	6	6	8	5	31
			Mean (SD)	2.3 (3.3)	1.7 (1.2)	1.8 (1.3)	3.3 (2.3)	2.6 (2.1)	2.4 (2.1)
			Min	1	1	1	1	1	1
			Median	1.0	1.0	1.0	3.0	2.0	1.0
			Max	9	4	4	7	6	9
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
	Myalgia	Time from dose to first systemic reaction [Days]	n	2	3	3	2	2	12
			Mean (SD)	2.0 (-)	1.0 (0.0)	1.3 (0.6)	2.0 (-)	1.0 (-)	1.4 (0.5)
			Min	2	1	1	2	1	1
			Median	2.0	1.0	1.0	2.0	1.0	1.0
			Max	2	1	2	2	1	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Myalgia	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
		Time from first systemic reaction to last systemic reaction [Days]	n	2	3	3	2	2	12
			Mean (SD)	1.5 (-)	1.0 (0.0)	1.7 (1.2)	2.0 (-)	2.0 (-)	1.6 (0.8)
			Min	1	1	1	1	2	1
			Median	1.5	1.0	1.0	2.0	2.0	1.0
			Max	2	1	3	3	2	3
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Arthralgia	Time from dose to first systemic reaction [Days]	n	1	1	3	2	0	7
			Mean (SD)	2.0 (-)	2.0 (-)	2.7 (2.1)	2.0 (-)	- (-)	2.3 (1.3)
			Min	2	2	1	2	-	1
			Median	2.0	2.0	2.0	2.0	-	2.0
			Max	2	2	5	2	-	5
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
		Time from first systemic reaction to last systemic reaction [Days]	n	1	1	3	2	0	7
			Mean (SD)	2.0 (-)	1.0 (-)	1.0 (0.0)	2.0 (-)	- (-)	1.4 (0.8)
			Min	2	1	1	1	-	1
			Median	2.0	1.0	1.0	2.0	-	1.0
			Max	2	1	1	3	-	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Arthralgia	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
	Chills	Time from dose to first systemic reaction [Days]	n	1	0	1	0	1	3
			Mean (SD)	2.0 (-)	- (-)	2.0 (-)	- (-)	2.0 (-)	2.0 (0.0)
			Min	2	-	2	-	2	2
			Median	2.0	-	2.0	-	2.0	2.0
			Max	2	-	2	-	2	2
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Chills	Time from first systemic reaction to last systemic reaction [Days]	n	1	0	1	0	1	3
			Mean (SD)	2.0 (-)	- (-)	1.0 (-)	- (-)	1.0 (-)	1.3 (0.6)
			Min	2	-	1	-	1	1
			Median	2.0	-	1.0	-	1.0	1.0
			Max	2	-	1	-	1	2
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
	Loss of Appetite	Time from dose to first systemic reaction [Days]	n	1	0	1	0	0	2
			Mean (SD)	3.0 (-)	- (-)	1.0 (-)	- (-)	- (-)	2.0 (-)
			Min	3	-	1	-	-	1
			Median	3.0	-	1.0	-	-	2.0
			Max	3	-	1	-	-	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Loss of Appetite	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
		Time from first systemic reaction to last systemic reaction [Days]	n	1	0	1	0	0	2
			Mean (SD)	1.0 (-)	- (-)	1.0 (-)	- (-)	- (-)	1.0 (-)
			Min	1	-	1	-	-	1
			Median	1.0	-	1.0	-	-	1.0
			Max	1	-	1	-	-	1
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Malaise	Time from dose to first systemic reaction [Days]	n	4	5	1	1	4	15
			Mean (SD)	2.3 (1.3)	2.2 (0.4)	1.0 (-)	2.0 (-)	1.3 (0.5)	1.9 (0.8)
			Min	1	2	1	2	1	1
			Median	2.0	2.0	1.0	2.0	1.0	2.0
			Max	4	3	1	2	2	4
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
		Time from first systemic reaction to last systemic reaction [Days]	n	4	5	1	1	4	15
			Mean (SD)	3.0 (3.4)	1.0 (0.0)	1.0 (-)	1.0 (-)	1.8 (1.0)	1.7 (1.8)
			Min	1	1	1	1	1	1
			Median	1.5	1.0	1.0	1.0	1.5	1.0
			Max	8	1	1	1	3	8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Malaise	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
	Fever	Time from dose to first systemic reaction [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Fever	Time from first systemic reaction to last systemic reaction [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
After boost	Nausea	Time from dose to first systemic reaction [Days]	n	0	1	0	1	1	3
			Mean (SD)	- (-)	1.0 (-)	- (-)	1.0 (-)	2.0 (-)	1.3 (0.6)
			Min	-	1	-	1	2	1
			Median	-	1.0	-	1.0	2.0	1.0
			Max	-	1	-	1	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Nausea	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	1	1
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	2.0 (-)	2.0 (-)
			Min	-	-	-	-	2	2
			Median	-	-	-	-	2.0	2.0
			Max	-	-	-	-	2	2
		Time from first systemic reaction to last systemic reaction [Days]	n	0	1	0	1	1	3
			Mean (SD)	- (-)	1.0 (-)	- (-)	1.0 (-)	1.0 (-)	1.0 (0.0)
			Min	-	1	-	1	1	1
			Median	-	1.0	-	1.0	1.0	1.0
			Max	-	1	-	1	1	1
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	1	1
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (-)	1.0 (-)
			Min	-	-	-	-	1	1
			Median	-	-	-	-	1.0	1.0
			Max	-	-	-	-	1	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Vomiting	Time from dose to first systemic reaction [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
		Time from first systemic reaction to last systemic reaction [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Vomiting	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
	Diarrhea	Time from dose to first systemic reaction [Days]	n	1	1	1	1	0	4
			Mean (SD)	5.0 (-)	6.0 (-)	1.0 (-)	2.0 (-)	- (-)	3.5 (2.4)
			Min	5	6	1	2	-	1
			Median	5.0	6.0	1.0	2.0	-	3.5
			Max	5	6	1	2	-	6
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Diarrhea	Time from first systemic reaction to last systemic reaction [Days]	n	1	1	1	1	0	4
			Mean (SD)	3.0 (-)	3.0 (-)	1.0 (-)	4.0 (-)	- (-)	2.8 (1.3)
			Min	3	3	1	4	-	1
			Median	3.0	3.0	1.0	4.0	-	3.0
			Max	3	3	1	4	-	4
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
	Headache	Time from dose to first systemic reaction [Days]	n	0	2	7	6	5	20
			Mean (SD)	- (-)	4.0 (-)	1.7 (0.8)	1.3 (0.5)	1.8 (0.4)	1.9 (1.3)
			Min	-	1	1	1	1	1
			Median	-	4.0	2.0	1.0	2.0	2.0
			Max	-	7	3	2	2	7

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Headache	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
		Time from first systemic reaction to last systemic reaction [Days]	n	0	2	7	6	5	20
			Mean (SD)	- (-)	5.5 (-)	1.1 (0.4)	1.7 (0.8)	1.4 (0.5)	1.8 (1.6)
			Min	-	3	1	1	1	1
			Median	-	5.5	1.0	1.5	1.0	1.0
			Max	-	8	2	3	2	8
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Fatigue	Time from dose to first systemic reaction [Days]	n	4	1	5	4	8	22
			Mean (SD)	1.0 (0.0)	8.0 (-)	1.8 (1.3)	1.5 (0.6)	1.5 (0.5)	1.8 (1.6)
			Min	1	8	1	1	1	1
			Median	1.0	8.0	1.0	1.5	1.5	1.0
			Max	1	8	4	2	2	8
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	1	2	3
			Mean (SD)	- (-)	- (-)	- (-)	2.0 (-)	3.5 (-)	3.0 (1.7)
			Min	-	-	-	2	2	2
			Median	-	-	-	2.0	3.5	2.0
			Max	-	-	-	2	5	5
		Time from first systemic reaction to last systemic reaction [Days]	n	4	1	5	4	8	22
			Mean (SD)	1.0 (0.0)	1.0 (-)	1.6 (0.9)	2.3 (1.3)	2.3 (1.7)	1.8 (1.3)
			Min	1	1	1	1	1	1
			Median	1.0	1.0	1.0	2.0	2.0	1.0
			Max	1	1	3	4	6	6

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Fatigue	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	1	2	3
			Mean (SD)	- (-)	- (-)	- (-)	1.0 (-)	1.0 (-)	1.0 (0.0)
			Min	-	-	-	1	1	1
			Median	-	-	-	1.0	1.0	1.0
			Max	-	-	-	1	1	1
	Myalgia	Time from dose to first systemic reaction [Days]	n	0	1	3	6	6	16
			Mean (SD)	- (-)	1.0 (-)	1.7 (0.6)	1.7 (0.5)	1.5 (0.5)	1.6 (0.5)
			Min	-	1	1	1	1	1
			Median	-	1.0	2.0	2.0	1.5	2.0
			Max	-	1	2	2	2	2
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	1	0	2	3
			Mean (SD)	- (-)	- (-)	1.0 (-)	- (-)	3.0 (-)	2.3 (1.5)
			Min	-	-	1	-	2	1
			Median	-	-	1.0	-	3.0	2.0
			Max	-	-	1	-	4	4

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Myalgia	Time from first systemic reaction to last systemic reaction [Days]	n	0	1	3	6	6	16
			Mean (SD)	- (-)	2.0 (-)	1.0 (0.0)	2.2 (2.0)	2.2 (1.6)	1.9 (1.6)
			Min	-	2	1	1	1	1
			Median	-	2.0	1.0	1.0	1.5	1.0
			Max	-	2	1	6	5	6
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	1	0	2	3
			Mean (SD)	- (-)	- (-)	1.0 (-)	- (-)	1.5 (-)	1.3 (0.6)
			Min	-	-	1	-	1	1
			Median	-	-	1.0	-	1.5	1.0
			Max	-	-	1	-	2	2
	Arthralgia	Time from dose to first systemic reaction [Days]	n	0	0	4	2	6	12
			Mean (SD)	- (-)	- (-)	1.8 (0.5)	1.5 (-)	1.7 (0.5)	1.7 (0.5)
			Min	-	-	1	1	1	1
			Median	-	-	2.0	1.5	2.0	2.0
			Max	-	-	2	2	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Arthralgia	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	3	3
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	2.7 (1.2)	2.7 (1.2)
			Min	-	-	-	-	2	2
			Median	-	-	-	-	2.0	2.0
			Max	-	-	-	-	4	4
		Time from first systemic reaction to last systemic reaction [Days]	n	0	0	4	2	6	12
			Mean (SD)	- (-)	- (-)	1.0 (0.0)	2.5 (-)	2.5 (1.4)	2.0 (1.3)
			Min	-	-	1	1	1	1
			Median	-	-	1.0	2.5	2.0	1.5
			Max	-	-	1	4	5	5
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	3	3
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.3 (0.6)	1.3 (0.6)
			Min	-	-	-	-	1	1
			Median	-	-	-	-	1.0	1.0
			Max	-	-	-	-	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Chills	Time from dose to first systemic reaction [Days]	n	0	0	2	4	6	12
			Mean (SD)	- (-)	- (-)	1.5 (-)	1.5 (0.6)	2.0 (0.0)	1.8 (0.5)
			Min	-	-	1	1	2	1
			Median	-	-	1.5	1.5	2.0	2.0
			Max	-	-	2	2	2	2
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	1	1	2
			Mean (SD)	- (-)	- (-)	- (-)	2.0 (-)	2.0 (-)	2.0 (-)
			Min	-	-	-	2	2	2
			Median	-	-	-	2.0	2.0	2.0
			Max	-	-	-	2	2	2
		Time from first systemic reaction to last systemic reaction [Days]	n	0	0	2	4	6	12
			Mean (SD)	- (-)	- (-)	1.0 (-)	1.0 (0.0)	1.0 (0.0)	1.0 (0.0)
			Min	-	-	1	1	1	1
			Median	-	-	1.0	1.0	1.0	1.0
			Max	-	-	1	1	1	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Chills	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	1	1	2
			Mean (SD)	- (-)	- (-)	- (-)	1.0 (-)	1.0 (-)	1.0 (-)
			Min	-	-	-	1	1	1
			Median	-	-	-	1.0	1.0	1.0
			Max	-	-	-	1	1	1
	Loss of Appetite	Time from dose to first systemic reaction [Days]	n	0	1	0	1	2	4
			Mean (SD)	- (-)	8.0 (-)	- (-)	2.0 (-)	2.0 (-)	3.5 (3.0)
			Min	-	8	-	2	2	2
			Median	-	8.0	-	2.0	2.0	2.0
			Max	-	8	-	2	2	8
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Loss of Appetite	Time from first systemic reaction to last systemic reaction [Days]	n	0	1	0	1	2	4
			Mean (SD)	- (-)	1.0 (-)	- (-)	1.0 (-)	1.0 (-)	1.0 (0.0)
			Min	-	1	-	1	1	1
			Median	-	1.0	-	1.0	1.0	1.0
			Max	-	1	-	1	1	1
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
	Malaise	Time from dose to first systemic reaction [Days]	n	0	2	3	4	6	15
			Mean (SD)	- (-)	1.5 (-)	1.7 (0.6)	1.5 (0.6)	2.0 (1.1)	1.7 (0.8)
			Min	-	1	1	1	1	1
			Median	-	1.5	2.0	1.5	2.0	2.0
			Max	-	2	2	2	4	4

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Malaise	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	1	0	1	2
			Mean (SD)	- (-)	- (-)	1.0 (-)	- (-)	5.0 (-)	3.0 (-)
			Min	-	-	1	-	5	1
			Median	-	-	1.0	-	5.0	3.0
			Max	-	-	1	-	5	5
		Time from first systemic reaction to last systemic reaction [Days]	n	0	2	3	4	6	15
			Mean (SD)	- (-)	4.0 (-)	1.0 (0.0)	1.0 (0.0)	1.7 (0.5)	1.7 (1.5)
			Min	-	1	1	1	1	1
			Median	-	4.0	1.0	1.0	2.0	1.0
			Max	-	7	1	1	2	7
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	1	0	1	2
			Mean (SD)	- (-)	- (-)	1.0 (-)	- (-)	1.0 (-)	1.0 (-)
			Min	-	-	1	-	1	1
			Median	-	-	1.0	-	1.0	1.0
			Max	-	-	1	-	1	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Fever	Time from dose to first systemic reaction [Days]	n	0	0	1	1	0	2
			Mean (SD)	- (-)	- (-)	2.0 (-)	2.0 (-)	- (-)	2.0 (-)
			Min	-	-	2	2	-	2
			Median	-	-	2.0	2.0	-	2.0
			Max	-	-	2	2	-	2
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-
		Time from first systemic reaction to last systemic reaction [Days]	n	0	0	1	1	0	2
			Mean (SD)	- (-)	- (-)	1.0 (-)	1.0 (-)	- (-)	1.0 (-)
			Min	-	-	1	1	-	1
			Median	-	-	1.0	1.0	-	1.0
			Max	-	-	1	1	-	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Younger dose ranging cohorts					
				1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Fever	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-	-
			Median	-	-	-	-	-	-
			Max	-	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Nausea	Time from dose to first systemic reaction [Days]	n	2	0	1	3	11
			Mean (SD)	4.0 (-)	- (-)	3.0 (-)	3.7 (1.2)	2.6 (1.7)
			Min	3	-	3	3	1
			Median	4.0	-	3.0	3.0	3.0
			Max	5	-	3	5	6
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from first systemic reaction to last systemic reaction [Days]	n	2	0	1	3	11
			Mean (SD)	1.0 (-)	- (-)	1.0 (-)	1.0 (0.0)	1.2 (0.6)
			Min	1	-	1	1	1
			Median	1.0	-	1.0	1.0	1.0
			Max	1	-	1	1	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Nausea	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
	Vomiting	Time from dose to first systemic reaction [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Vomiting	Time from first systemic reaction to last systemic reaction [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
	Diarrhea	Time from dose to first systemic reaction [Days]	n	1	0	1	2	8
			Mean (SD)	6.0 (-)	- (-)	3.0 (-)	4.5 (-)	4.4 (2.0)
			Min	6	-	3	3	2
			Median	6.0	-	3.0	4.5	4.0
			Max	6	-	3	6	8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Diarrhea	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from first systemic reaction to last systemic reaction [Days]	n	1	0	1	2	8
			Mean (SD)	1.0 (-)	- (-)	1.0 (-)	1.0 (-)	1.1 (0.4)
			Min	1	-	1	1	1
			Median	1.0	-	1.0	1.0	1.0
			Max	1	-	1	1	2
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Headache	Time from dose to first systemic reaction [Days]	n	2	3	5	10	34
			Mean (SD)	3.5 (-)	1.7 (0.6)	1.2 (0.4)	1.8 (1.0)	1.9 (1.3)
			Min	3	1	1	1	1
			Median	3.5	2.0	1.0	1.5	2.0
			Max	4	2	2	4	7
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	1
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	2.0 (-)
			Min	-	-	-	-	2
			Median	-	-	-	-	2.0
			Max	-	-	-	-	2
		Time from first systemic reaction to last systemic reaction [Days]	n	2	3	5	10	34
			Mean (SD)	4.0 (-)	1.3 (0.6)	2.4 (2.6)	2.4 (2.1)	2.3 (2.1)
			Min	3	1	1	1	1
			Median	4.0	1.0	1.0	1.5	1.0
			Max	5	2	7	7	8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Headache	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	1
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (-)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	1
	Fatigue	Time from dose to first systemic reaction [Days]	n	3	3	7	13	44
			Mean (SD)	1.0 (0.0)	1.3 (0.6)	2.0 (1.2)	1.6 (1.0)	1.8 (1.4)
			Min	1	1	1	1	1
			Median	1.0	1.0	2.0	1.0	1.0
			Max	1	2	4	4	7
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	1	0	0	1	1
			Mean (SD)	1.0 (-)	- (-)	- (-)	1.0 (-)	1.0 (-)
			Min	1	-	-	1	1
			Median	1.0	-	-	1.0	1.0
			Max	1	-	-	1	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Fatigue	Time from first systemic reaction to last systemic reaction [Days]	n	3	3	7	13	44
			Mean (SD)	5.3 (2.1)	2.0 (0.0)	1.1 (0.4)	2.3 (2.0)	2.4 (2.1)
			Min	3	2	1	1	1
			Median	6.0	2.0	1.0	2.0	1.0
			Max	7	2	2	7	9
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	1	0	0	1	1
			Mean (SD)	1.0 (-)	- (-)	- (-)	1.0 (-)	1.0 (-)
			Min	1	-	-	1	1
			Median	1.0	-	-	1.0	1.0
			Max	1	-	-	1	1
	Myalgia	Time from dose to first systemic reaction [Days]	n	1	0	2	3	15
			Mean (SD)	1.0 (-)	- (-)	2.5 (-)	2.0 (1.7)	1.5 (0.8)
			Min	1	-	1	1	1
			Median	1.0	-	2.5	1.0	1.0
			Max	1	-	4	4	4

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Myalgia	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from first systemic reaction to last systemic reaction [Days]	n	1	0	2	3	15
			Mean (SD)	1.0 (-)	- (-)	1.5 (-)	1.3 (0.6)	1.5 (0.7)
			Min	1	-	1	1	1
			Median	1.0	-	1.5	1.0	1.0
			Max	1	-	2	2	3
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Arthralgia	Time from dose to first systemic reaction [Days]	n	1	0	0	1	8
			Mean (SD)	6.0 (-)	- (-)	- (-)	6.0 (-)	2.8 (1.8)
			Min	6	-	-	6	1
			Median	6.0	-	-	6.0	2.0
			Max	6	-	-	6	6
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from first systemic reaction to last systemic reaction [Days]	n	1	0	0	1	8
			Mean (SD)	2.0 (-)	- (-)	- (-)	2.0 (-)	1.5 (0.8)
			Min	2	-	-	2	1
			Median	2.0	-	-	2.0	1.0
			Max	2	-	-	2	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Arthralgia	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
	Chills	Time from dose to first systemic reaction [Days]	n	0	0	1	1	4
			Mean (SD)	- (-)	- (-)	3.0 (-)	3.0 (-)	2.3 (0.5)
			Min	-	-	3	3	2
			Median	-	-	3.0	3.0	2.0
			Max	-	-	3	3	3
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Chills	Time from first systemic reaction to last systemic reaction [Days]	n	0	0	1	1	4
			Mean (SD)	- (-)	- (-)	1.0 (-)	1.0 (-)	1.3 (0.5)
			Min	-	-	1	1	1
			Median	-	-	1.0	1.0	1.0
			Max	-	-	1	1	2
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
	Loss of Appetite	Time from dose to first systemic reaction [Days]	n	1	0	0	1	3
			Mean (SD)	5.0 (-)	- (-)	- (-)	5.0 (-)	3.0 (2.0)
			Min	5	-	-	5	1
			Median	5.0	-	-	5.0	3.0
			Max	5	-	-	5	5

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Loss of Appetite	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from first systemic reaction to last systemic reaction [Days]	n	1	0	0	1	3
			Mean (SD)	3.0 (-)	- (-)	- (-)	3.0 (-)	1.7 (1.2)
			Min	3	-	-	3	1
			Median	3.0	-	-	3.0	1.0
			Max	3	-	-	3	3
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Malaise	Time from dose to first systemic reaction [Days]	n	2	1	2	5	20
			Mean (SD)	4.0 (-)	2.0 (-)	2.0 (-)	2.8 (1.5)	2.1 (1.1)
			Min	3	2	1	1	1
			Median	4.0	2.0	2.0	3.0	2.0
			Max	5	2	3	5	5
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from first systemic reaction to last systemic reaction [Days]	n	2	1	2	5	20
			Mean (SD)	2.0 (-)	1.0 (-)	1.0 (-)	1.4 (0.9)	1.7 (1.6)
			Min	1	1	1	1	1
			Median	2.0	1.0	1.0	1.0	1.0
			Max	3	1	1	3	8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Malaise	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
	Fever	Time from dose to first systemic reaction [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After prime	Fever	Time from first systemic reaction to last systemic reaction [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
After boost	Nausea	Time from dose to first systemic reaction [Days]	n	2	0	2	4	7
			Mean (SD)	1.5 (-)	- (-)	2.0 (-)	1.8 (0.5)	1.6 (0.5)
			Min	1	-	2	1	1
			Median	1.5	-	2.0	2.0	2.0
			Max	2	-	2	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After boost	Nausea	Time from dose to first systemic reaction with grade >= 3 [Days]	n	1	0	0	1	2
			Mean (SD)	1.0 (-)	- (-)	- (-)	1.0 (-)	1.5 (-)
			Min	1	-	-	1	1
			Median	1.0	-	-	1.0	1.5
			Max	1	-	-	1	2
		Time from first systemic reaction to last systemic reaction [Days]	n	2	0	2	4	7
			Mean (SD)	1.0 (-)	- (-)	1.0 (-)	1.0 (0.0)	1.0 (0.0)
			Min	1	-	1	1	1
			Median	1.0	-	1.0	1.0	1.0
			Max	1	-	1	1	1
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	1	0	0	1	2
			Mean (SD)	1.0 (-)	- (-)	- (-)	1.0 (-)	1.0 (-)
			Min	1	-	-	1	1
			Median	1.0	-	-	1.0	1.0
			Max	1	-	-	1	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After boost	Vomiting	Time from dose to first systemic reaction [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from first systemic reaction to last systemic reaction [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After boost	Vomiting	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
	Diarrhea	Time from dose to first systemic reaction [Days]	n	0	0	1	1	5
			Mean (SD)	- (-)	- (-)	3.0 (-)	3.0 (-)	3.4 (2.1)
			Min	-	-	3	3	1
			Median	-	-	3.0	3.0	3.0
			Max	-	-	3	3	6
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After boost	Diarrhea	Time from first systemic reaction to last systemic reaction [Days]	n	0	0	1	1	5
			Mean (SD)	- (-)	- (-)	1.0 (-)	1.0 (-)	2.4 (1.3)
			Min	-	-	1	1	1
			Median	-	-	1.0	1.0	3.0
			Max	-	-	1	1	4
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
	Headache	Time from dose to first systemic reaction [Days]	n	2	5	8	15	35
			Mean (SD)	1.0 (-)	2.2 (2.7)	1.3 (0.5)	1.5 (1.6)	1.7 (1.4)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	1	7	2	7	7

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After boost	Headache	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	1	1	1
			Mean (SD)	- (-)	- (-)	2.0 (-)	2.0 (-)	2.0 (-)
			Min	-	-	2	2	2
			Median	-	-	2.0	2.0	2.0
			Max	-	-	2	2	2
		Time from first systemic reaction to last systemic reaction [Days]	n	2	5	8	15	35
			Mean (SD)	4.0 (-)	1.8 (0.8)	1.9 (1.4)	2.1 (1.7)	1.9 (1.6)
			Min	1	1	1	1	1
			Median	4.0	2.0	1.5	2.0	1.0
			Max	7	3	5	7	8
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	1	1	1
			Mean (SD)	- (-)	- (-)	1.0 (-)	1.0 (-)	1.0 (-)
			Min	-	-	1	1	1
			Median	-	-	1.0	1.0	1.0
			Max	-	-	1	1	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After boost	Fatigue	Time from dose to first systemic reaction [Days]	n	3	6	7	16	38
			Mean (SD)	1.0 (0.0)	1.3 (0.5)	1.3 (0.5)	1.3 (0.4)	1.6 (1.2)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	1	2	2	2	8
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	3
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	3.0 (1.7)
			Min	-	-	-	-	2
			Median	-	-	-	-	2.0
			Max	-	-	-	-	5
		Time from first systemic reaction to last systemic reaction [Days]	n	3	6	7	16	38
			Mean (SD)	2.0 (1.0)	2.0 (1.3)	1.6 (0.8)	1.8 (1.0)	1.8 (1.1)
			Min	1	1	1	1	1
			Median	2.0	1.5	1.0	1.5	1.0
			Max	3	4	3	4	6

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After boost	Fatigue	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	3
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (0.0)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	1
	Myalgia	Time from dose to first systemic reaction [Days]	n	2	4	4	10	26
			Mean (SD)	1.5 (-)	1.0 (0.0)	1.8 (0.5)	1.4 (0.5)	1.5 (0.5)
			Min	1	1	1	1	1
			Median	1.5	1.0	2.0	1.0	1.5
			Max	2	1	2	2	2
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	3
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	2.3 (1.5)
			Min	-	-	-	-	1
			Median	-	-	-	-	2.0
			Max	-	-	-	-	4

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After boost	Myalgia	Time from first systemic reaction to last systemic reaction [Days]	n	2	4	4	10	26
			Mean (SD)	1.0 (-)	2.0 (0.8)	1.0 (0.0)	1.4 (0.7)	1.7 (1.3)
			Min	1	1	1	1	1
			Median	1.0	2.0	1.0	1.0	1.0
			Max	1	3	1	3	6
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	3
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.3 (0.6)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	2
	Arthralgia	Time from dose to first systemic reaction [Days]	n	0	1	3	4	16
			Mean (SD)	- (-)	1.0 (-)	1.7 (0.6)	1.5 (0.6)	1.6 (0.5)
			Min	-	1	1	1	1
			Median	-	1.0	2.0	1.5	2.0
			Max	-	1	2	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After boost	Arthralgia	Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	3
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	2.7 (1.2)
			Min	-	-	-	-	2
			Median	-	-	-	-	2.0
			Max	-	-	-	-	4
		Time from first systemic reaction to last systemic reaction [Days]	n	0	1	3	4	16
			Mean (SD)	- (-)	2.0 (-)	1.0 (0.0)	1.3 (0.5)	1.8 (1.2)
			Min	-	2	1	1	1
			Median	-	2.0	1.0	1.0	1.0
			Max	-	2	1	2	5
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	3
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.3 (0.6)
			Min	-	-	-	-	1
			Median	-	-	-	-	1.0
			Max	-	-	-	-	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After boost	Chills	Time from dose to first systemic reaction [Days]	n	0	1	4	5	17
			Mean (SD)	- (-)	2.0 (-)	1.3 (0.5)	1.4 (0.5)	1.6 (0.5)
			Min	-	2	1	1	1
			Median	-	2.0	1.0	1.0	2.0
			Max	-	2	2	2	2
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	1	1	3
			Mean (SD)	- (-)	- (-)	1.0 (-)	1.0 (-)	1.7 (0.6)
			Min	-	-	1	1	1
			Median	-	-	1.0	1.0	2.0
			Max	-	-	1	1	2
		Time from first systemic reaction to last systemic reaction [Days]	n	0	1	4	5	17
			Mean (SD)	- (-)	1.0 (-)	1.8 (0.5)	1.6 (0.5)	1.2 (0.4)
			Min	-	1	1	1	1
			Median	-	1.0	2.0	2.0	1.0
			Max	-	1	2	2	2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After boost	Chills	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	1	1	3
			Mean (SD)	- (-)	- (-)	2.0 (-)	2.0 (-)	1.3 (0.6)
			Min	-	-	2	2	1
			Median	-	-	2.0	2.0	1.0
			Max	-	-	2	2	2
	Loss of Appetite	Time from dose to first systemic reaction [Days]	n	1	1	3	5	9
			Mean (SD)	4.0 (-)	3.0 (-)	1.7 (0.6)	2.4 (1.1)	2.9 (2.1)
			Min	4	3	1	1	1
			Median	4.0	3.0	2.0	2.0	2.0
			Max	4	3	2	4	8
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After boost	Loss of Appetite	Time from first systemic reaction to last systemic reaction [Days]	n	1	1	3	5	9
			Mean (SD)	1.0 (-)	2.0 (-)	1.7 (0.6)	1.6 (0.5)	1.3 (0.5)
			Min	1	2	1	1	1
			Median	1.0	2.0	2.0	2.0	1.0
			Max	1	2	2	2	2
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
	Malaise	Time from dose to first systemic reaction [Days]	n	2	1	5	8	23
			Mean (SD)	1.5 (-)	1.0 (-)	1.8 (0.4)	1.6 (0.5)	1.7 (0.7)
			Min	1	1	1	1	1
			Median	1.5	1.0	2.0	2.0	2.0
			Max	2	1	2	2	4

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After boost	Malaise	Time from dose to first systemic reaction with grade >= 3 [Days]	n	1	0	0	1	3
			Mean (SD)	1.0 (-)	- (-)	- (-)	1.0 (-)	2.3 (2.3)
			Min	1	-	-	1	1
			Median	1.0	-	-	1.0	1.0
			Max	1	-	-	1	5
		Time from first systemic reaction to last systemic reaction [Days]	n	2	1	5	8	23
			Mean (SD)	1.0 (-)	1.0 (-)	1.2 (0.4)	1.1 (0.4)	1.5 (1.3)
			Min	1	1	1	1	1
			Median	1.0	1.0	1.0	1.0	1.0
			Max	1	1	2	2	7
		Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	1	0	0	1	3
			Mean (SD)	1.0 (-)	- (-)	- (-)	1.0 (-)	1.0 (0.0)
			Min	1	-	-	1	1
			Median	1.0	-	-	1.0	1.0
			Max	1	-	-	1	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After boost	Fever	Time from dose to first systemic reaction [Days]	n	0	0	3	3	5
			Mean (SD)	- (-)	- (-)	2.0 (0.0)	2.0 (0.0)	2.0 (0.0)
			Min	-	-	2	2	2
			Median	-	-	2.0	2.0	2.0
			Max	-	-	2	2	2
		Time from dose to first systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-
		Time from first systemic reaction to last systemic reaction [Days]	n	0	0	3	3	5
			Mean (SD)	- (-)	- (-)	1.0 (0.0)	1.0 (0.0)	1.0 (0.0)
			Min	-	-	1	1	1
			Median	-	-	1.0	1.0	1.0
			Max	-	-	1	1	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.5.2-3: Descriptive statistics of time of solicited systemic reactions by term - BNT162b2

Safety set

				Older dose ranging cohorts				
				10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
After boost	Fever	Time from first systemic reaction with grade >= 3 to last systemic reaction with grade >= 3 [Days]	n	0	0	0	0	0
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	- (-)
			Min	-	-	-	-	-
			Median	-	-	-	-	-
			Max	-	-	-	-	-

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; SD = standard deviation; - = not estimable.

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Table 14.3.1-2.6.1-3: Frequency of subjects with solicited systemic reactions per day - BNT162b2

Safety set

		Younger dose ranging cohorts					
	Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Any n	9	9	12	9	9	48
	Day 0 n (%)	6 (67)	7 (78)	8 (67)	6 (67)	4 (44)	31 (65)
	Day 1 n (%)	3 (33)	6 (67)	5 (42)	5 (56)	5 (56)	24 (50)
	Day 2 n (%)	3 (33)	1 (11)	6 (50)	3 (33)	2 (22)	15 (31)
	Day 3 n (%)	1 (11)	2 (22)	1 (8)	4 (44)	1 (11)	9 (19)
	Day 4 n (%)	1 (11)	2 (22)	1 (8)	4 (44)	2 (22)	10 (21)
	Day 5 n (%)	1 (11)	2 (22)	1 (8)	3 (33)	1 (11)	8 (17)
	Day 6 n (%)	1 (11)	1 (11)	0 (0)	1 (11)	2 (22)	5 (10)
	Day 7 n (%)	1 (11)	0 (0)	0 (0)	0 (0)	1 (11)	2 (4)
After boost	Any n	4	2	7	10	10	33
	Day 0 n (%)	4 (100)	2 (100)	6 (86)	6 (60)	5 (50)	23 (70)
	Day 1 n (%)	0 (0)	1 (50)	4 (57)	8 (80)	9 (90)	22 (67)
	Day 2 n (%)	0 (0)	0 (0)	2 (29)	4 (40)	5 (50)	11 (33)
	Day 3 n (%)	0 (0)	0 (0)	1 (14)	3 (30)	1 (10)	5 (15)
	Day 4 n (%)	1 (25)	0 (0)	0 (0)	3 (30)	1 (10)	5 (15)
	Day 5 n (%)	0 (0)	1 (50)	0 (0)	1 (10)	1 (10)	3 (9)
	Day 6 n (%)	1 (25)	1 (50)	0 (0)	1 (10)	0 (0)	3 (9)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 1 of 4)

Table 14.3.1-2.6.1-3: Frequency of subjects with solicited systemic reactions per day - BNT162b2

Safety set

		Younger dose ranging cohorts					
	Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Day 7 n (%)	0 (0)	2 (100)	0 (0)	0 (0)	0 (0)	2 (6)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

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Table 14.3.1-2.6.1-3: Frequency of subjects with solicited systemic reactions per day - BNT162b2

Safety set

		Older dose ranging cohorts				
	Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=16)	Total (N=96)
After prime	Any n	3	4	9	16	64
	Day 0 n (%)	3 (100)	2 (50)	5 (56)	10 (63)	41 (64)
	Day 1 n (%)	2 (67)	4 (100)	4 (44)	10 (63)	34 (53)
	Day 2 n (%)	2 (67)	1 (25)	2 (22)	5 (31)	20 (31)
	Day 3 n (%)	1 (33)	0 (0)	1 (11)	2 (13)	11 (17)
	Day 4 n (%)	1 (33)	0 (0)	1 (11)	2 (13)	12 (19)
	Day 5 n (%)	2 (67)	0 (0)	0 (0)	2 (13)	10 (16)
	Day 6 n (%)	2 (67)	0 (0)	1 (11)	3 (19)	8 (13)
	Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (3)
After boost	Any n	4	8	11	23	56
	Day 0 n (%)	4 (100)	5 (63)	8 (73)	17 (74)	40 (71)
	Day 1 n (%)	2 (50)	7 (88)	9 (82)	18 (78)	40 (71)
	Day 2 n (%)	1 (25)	2 (25)	1 (9)	4 (17)	15 (27)
	Day 3 n (%)	1 (25)	1 (13)	0 (0)	2 (9)	7 (13)
	Day 4 n (%)	0 (0)	0 (0)	1 (9)	1 (4)	6 (11)
	Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (5)
	Day 6 n (%)	1 (25)	1 (13)	0 (0)	2 (9)	5 (9)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 3 of 4)

Table 14.3.1-2.6.1-3: Frequency of subjects with solicited systemic reactions per day - BNT162b2

Safety set

		Older dose ranging cohorts				
	Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=16)	Total (N=96)
After boost	Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (4)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 4 of 4)

Table 14.3.1-2.6.2-3: Frequency of subjects with solicited systemic reactions by term per day - BNT162b2

Safety set

			Younger dose ranging cohorts					
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Nausea	Any n	1	0	5	0	2	8
		Day 0 n (%)	0 (0)	0 (0)	3 (60)	0 (0)	1 (50)	4 (50)
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (100)	2 (25)
		Day 2 n (%)	1 (100)	0 (0)	1 (20)	0 (0)	1 (50)	3 (38)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Day 5 n (%)	0 (0)	0 (0)	1 (20)	0 (0)	0 (0)	1 (13)
	Diarrhea	Any n	1	1	0	2	2	6
		Day 1 n (%)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	1 (17)
		Day 2 n (%)	1 (100)	0 (0)	0 (0)	1 (50)	0 (0)	2 (33)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	1 (50)	0 (0)	1 (17)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	1 (50)	1 (50)	2 (33)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (50)	1 (17)
	Headache	Any n	3	6	6	4	5	24
		Day 0 n (%)	2 (67)	3 (50)	3 (50)	1 (25)	2 (40)	11 (46)
		Day 1 n (%)	1 (33)	5 (83)	1 (17)	3 (75)	3 (60)	13 (54)
		Day 2 n (%)	1 (33)	1 (17)	2 (33)	1 (25)	1 (20)	6 (25)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 1 of 16)

Table 14.3.1-2.6.2-3: Frequency of subjects with solicited systemic reactions by term per day - BNT162b2

Safety set

			Younger dose ranging cohorts					
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Headache	Day 3 n (%)	0 (0)	1 (17)	1 (17)	1 (25)	0 (0)	3 (13)
		Day 4 n (%)	1 (33)	2 (33)	0 (0)	1 (25)	0 (0)	4 (17)
		Day 5 n (%)	1 (33)	1 (17)	0 (0)	2 (50)	0 (0)	4 (17)
		Day 6 n (%)	1 (33)	1 (17)	0 (0)	1 (25)	1 (20)	4 (17)
		Day 7 n (%)	1 (33)	0 (0)	0 (0)	0 (0)	0 (0)	1 (4)
	Fatigue	Any n	6	6	6	8	5	31
		Day 0 n (%)	5 (83)	4 (67)	3 (50)	6 (75)	3 (60)	21 (68)
		Day 1 n (%)	1 (17)	2 (33)	3 (50)	4 (50)	4 (80)	14 (45)
		Day 2 n (%)	1 (17)	1 (17)	3 (50)	1 (13)	2 (40)	8 (26)
		Day 3 n (%)	1 (17)	1 (17)	1 (17)	2 (25)	1 (20)	6 (19)
		Day 4 n (%)	1 (17)	0 (0)	1 (17)	4 (50)	1 (20)	7 (23)
		Day 5 n (%)	1 (17)	1 (17)	0 (0)	2 (25)	1 (20)	5 (16)
		Day 6 n (%)	1 (17)	0 (0)	0 (0)	1 (13)	1 (20)	3 (10)
		Day 7 n (%)	1 (17)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)
	Myalgia	Any n	2	3	3	2	2	12
		Day 0 n (%)	0 (0)	3 (100)	2 (67)	0 (0)	2 (100)	7 (58)
		Day 1 n (%)	2 (100)	0 (0)	2 (67)	2 (100)	2 (100)	8 (67)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 2 of 16)

Table 14.3.1-2.6.2-3: Frequency of subjects with solicited systemic reactions by term per day - BNT162b2

Safety set

			Younger dose ranging cohorts					
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Myalgia	Day 2 n (%)	1 (50)	0 (0)	1 (33)	1 (50)	0 (0)	3 (25)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	1 (50)	0 (0)	1 (8)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Arthralgia	Any n	1	1	3	2	0	7
		Day 0 n (%)	0 (0)	0 (0)	1 (33)	0 (0)	0 (0)	1 (14)
		Day 1 n (%)	1 (100)	1 (100)	1 (33)	2 (100)	0 (0)	5 (71)
		Day 2 n (%)	1 (100)	0 (0)	0 (0)	1 (50)	0 (0)	2 (29)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	1 (50)	0 (0)	1 (14)
		Day 4 n (%)	0 (0)	0 (0)	1 (33)	0 (0)	0 (0)	1 (14)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Chills	Any n	1	0	1	0	1	3
		Day 1 n (%)	1 (100)	0 (0)	1 (100)	0 (0)	1 (100)	3 (100)
		Day 2 n (%)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	1 (33)
	Loss of Appetite	Any n	1	0	1	0	0	2
		Day 0 n (%)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	1 (50)
		Day 2 n (%)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	1 (50)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 3 of 16)

Table 14.3.1-2.6.2-3: Frequency of subjects with solicited systemic reactions by term per day - BNT162b2

Safety set

			Younger dose ranging cohorts					
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After prime	Loss of Appetite	Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Malaise	Any n	4	5	1	1	4	15
		Day 0 n (%)	1 (25)	0 (0)	1 (100)	0 (0)	3 (75)	5 (33)
		Day 1 n (%)	2 (50)	4 (80)	0 (0)	1 (100)	3 (75)	10 (67)
		Day 2 n (%)	2 (50)	1 (20)	0 (0)	0 (0)	1 (25)	4 (27)
		Day 3 n (%)	1 (25)	0 (0)	0 (0)	0 (0)	0 (0)	1 (7)
		Day 4 n (%)	1 (25)	0 (0)	0 (0)	0 (0)	0 (0)	1 (7)
		Day 5 n (%)	1 (25)	0 (0)	0 (0)	0 (0)	0 (0)	1 (7)
		Day 6 n (%)	1 (25)	0 (0)	0 (0)	0 (0)	0 (0)	1 (7)
		Day 7 n (%)	1 (25)	0 (0)	0 (0)	0 (0)	0 (0)	1 (7)
After boost	Nausea	Any n	0	1	0	1	1	3
		Day 0 n (%)	0 (0)	1 (100)	0 (0)	1 (100)	0 (0)	2 (67)
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	1 (33)
	Diarrhea	Any n	1	1	1	1	0	4
		Day 0 n (%)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	1 (25)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 4 of 16)

Table 14.3.1-2.6.2-3: Frequency of subjects with solicited systemic reactions by term per day - BNT162b2

Safety set

			Younger dose ranging cohorts					
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Diarrhea	Day 1 n (%)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	1 (25)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	1 (25)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	1 (25)
		Day 4 n (%)	1 (100)	0 (0)	0 (0)	1 (100)	0 (0)	2 (50)
		Day 5 n (%)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	1 (25)
		Day 6 n (%)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	1 (25)
		Day 7 n (%)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	1 (25)
	Headache	Any n	0	2	7	6	5	20
		Day 0 n (%)	0 (0)	1 (50)	3 (43)	4 (67)	1 (20)	9 (45)
		Day 1 n (%)	0 (0)	0 (0)	3 (43)	5 (83)	5 (100)	13 (65)
		Day 2 n (%)	0 (0)	0 (0)	2 (29)	1 (17)	1 (20)	4 (20)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Day 6 n (%)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	1 (5)
		Day 7 n (%)	0 (0)	2 (100)	0 (0)	0 (0)	0 (0)	2 (10)
	Fatigue	Any n	4	1	5	4	8	22
		Day 0 n (%)	4 (100)	0 (0)	3 (60)	2 (50)	4 (50)	13 (59)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 5 of 16)

Table 14.3.1-2.6.2-3: Frequency of subjects with solicited systemic reactions by term per day - BNT162b2

Safety set

			Younger dose ranging cohorts					
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Fatigue	Day 1 n (%)	0 (0)	0 (0)	3 (60)	4 (100)	8 (100)	15 (68)
		Day 2 n (%)	0 (0)	0 (0)	1 (20)	1 (25)	3 (38)	5 (23)
		Day 3 n (%)	0 (0)	0 (0)	1 (20)	1 (25)	0 (0)	2 (9)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	1 (25)	1 (13)	2 (9)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)	1 (5)
		Day 7 n (%)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	1 (5)
	Myalgia	Any n	0	1	3	6	6	16
		Day 0 n (%)	0 (0)	1 (100)	1 (33)	2 (33)	3 (50)	7 (44)
		Day 1 n (%)	0 (0)	1 (100)	2 (67)	5 (83)	5 (83)	13 (81)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	2 (33)	2 (33)	4 (25)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	1 (17)	1 (17)	2 (13)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	1 (17)	1 (17)	2 (13)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	1 (17)	1 (17)	2 (13)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	1 (17)	0 (0)	1 (6)
	Arthralgia	Any n	0	0	4	2	6	12
		Day 0 n (%)	0 (0)	0 (0)	1 (25)	1 (50)	2 (33)	4 (33)
		Day 1 n (%)	0 (0)	0 (0)	3 (75)	1 (50)	6 (100)	10 (83)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 6 of 16)

Table 14.3.1-2.6.2-3: Frequency of subjects with solicited systemic reactions by term per day - BNT162b2

Safety set

			Younger dose ranging cohorts					
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Arthralgia	Day 2 n (%)	0 (0)	0 (0)	0 (0)	1 (50)	4 (67)	5 (42)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	1 (50)	1 (17)	2 (17)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	1 (50)	1 (17)	2 (17)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (17)	1 (8)
	Chills	Any n	0	0	2	4	6	12
		Day 0 n (%)	0 (0)	0 (0)	1 (50)	2 (50)	0 (0)	3 (25)
		Day 1 n (%)	0 (0)	0 (0)	1 (50)	2 (50)	6 (100)	9 (75)
	Loss of Appetite	Any n	0	1	0	1	2	4
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	1 (100)	2 (100)	3 (75)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Day 7 n (%)	0 (0)	1 (100)	0 (0)	0 (0)	0 (0)	1 (25)
	Malaise	Any n	0	2	3	4	6	15
		Day 0 n (%)	0 (0)	1 (50)	1 (33)	2 (50)	2 (33)	6 (40)
		Day 1 n (%)	0 (0)	1 (50)	2 (67)	2 (50)	5 (83)	10 (67)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (17)	1 (7)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

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Table 14.3.1-2.6.2-3: Frequency of subjects with solicited systemic reactions by term per day - BNT162b2

Safety set

			Younger dose ranging cohorts					
		Day after immunization	1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
After boost	Malaise	Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (17)	1 (7)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (17)	1 (7)
		Day 7 n (%)	0 (0)	1 (50)	0 (0)	0 (0)	0 (0)	1 (7)
	Fever	Any n	0	0	1	1	0	2
		Day 1 n (%)	0 (0)	0 (0)	1 (100)	1 (100)	0 (0)	2 (100)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

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Table 14.3.1-2.6.2-3: Frequency of subjects with solicited systemic reactions by term per day - BNT162b2

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=16)	Total (N=96)
After prime	Nausea	Any n	2	0	1	3	11
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	4 (36)
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (18)
		Day 2 n (%)	1 (50)	0 (0)	1 (100)	2 (67)	5 (45)
		Day 4 n (%)	1 (50)	0 (0)	0 (0)	1 (33)	1 (9)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (9)
	Diarrhea	Any n	1	0	1	2	8
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)
		Day 2 n (%)	0 (0)	0 (0)	1 (100)	1 (50)	3 (38)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (25)
		Day 5 n (%)	1 (100)	0 (0)	0 (0)	1 (50)	1 (13)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)
	Headache	Any n	2	3	5	10	34
		Day 0 n (%)	0 (0)	1 (33)	4 (80)	5 (50)	16 (47)
		Day 1 n (%)	0 (0)	2 (67)	1 (20)	3 (30)	16 (47)
		Day 2 n (%)	1 (50)	1 (33)	1 (20)	3 (30)	9 (26)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

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Table 14.3.1-2.6.2-3: Frequency of subjects with solicited systemic reactions by term per day - BNT162b2

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=16)	Total (N=96)
After prime	Headache	Day 3 n (%)	1 (50)	0 (0)	0 (0)	1 (10)	4 (12)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	4 (12)
		Day 5 n (%)	1 (50)	0 (0)	0 (0)	1 (10)	5 (15)
		Day 6 n (%)	1 (50)	0 (0)	1 (20)	2 (20)	6 (18)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)
	Fatigue	Any n	3	3	7	13	44
		Day 0 n (%)	3 (100)	2 (67)	3 (43)	8 (62)	29 (66)
		Day 1 n (%)	2 (67)	3 (100)	3 (43)	8 (62)	22 (50)
		Day 2 n (%)	2 (67)	1 (33)	1 (14)	4 (31)	12 (27)
		Day 3 n (%)	1 (33)	0 (0)	1 (14)	2 (15)	8 (18)
		Day 4 n (%)	1 (33)	0 (0)	0 (0)	1 (8)	8 (18)
		Day 5 n (%)	2 (67)	0 (0)	0 (0)	2 (15)	7 (16)
		Day 6 n (%)	1 (33)	0 (0)	0 (0)	1 (8)	4 (9)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
	Myalgia	Any n	1	0	2	3	15
		Day 0 n (%)	1 (100)	0 (0)	1 (50)	2 (67)	9 (60)
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	8 (53)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

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Table 14.3.1-2.6.2-3: Frequency of subjects with solicited systemic reactions by term per day - BNT162b2

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=16)	Total (N=96)
After prime	Myalgia	Day 2 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (20)
		Day 3 n (%)	0 (0)	0 (0)	1 (50)	1 (33)	2 (13)
		Day 4 n (%)	0 (0)	0 (0)	1 (50)	1 (33)	1 (7)
	Arthralgia	Any n	1	0	0	1	8
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	5 (63)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (25)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (13)
		Day 5 n (%)	1 (100)	0 (0)	0 (0)	1 (100)	1 (13)
		Day 6 n (%)	1 (100)	0 (0)	0 (0)	1 (100)	1 (13)
	Chills	Any n	0	0	1	1	4
		Day 1 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	3 (75)
		Day 2 n (%)	0 (0)	0 (0)	1 (100)	1 (100)	2 (50)
	Loss of Appetite	Any n	1	0	0	1	3
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (33)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (33)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 11 of 16)

Table 14.3.1-2.6.2-3: Frequency of subjects with solicited systemic reactions by term per day - BNT162b2

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=16)	Total (N=96)
After prime	Loss of Appetite	Day 4 n (%)	1 (100)	0 (0)	0 (0)	1 (100)	1 (33)
		Day 5 n (%)	1 (100)	0 (0)	0 (0)	1 (100)	1 (33)
		Day 6 n (%)	1 (100)	0 (0)	0 (0)	1 (100)	1 (33)
	Malaise	Any n	2	1	2	5	20
		Day 0 n (%)	0 (0)	0 (0)	1 (50)	1 (20)	6 (30)
		Day 1 n (%)	0 (0)	1 (100)	0 (0)	1 (20)	11 (55)
		Day 2 n (%)	1 (50)	0 (0)	1 (50)	2 (40)	6 (30)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)
		Day 4 n (%)	1 (50)	0 (0)	0 (0)	1 (20)	2 (10)
		Day 5 n (%)	1 (50)	0 (0)	0 (0)	1 (20)	2 (10)
		Day 6 n (%)	1 (50)	0 (0)	0 (0)	1 (20)	2 (10)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)
After boost	Nausea	Any n	2	0	2	4	7
		Day 0 n (%)	1 (50)	0 (0)	0 (0)	1 (25)	3 (43)
		Day 1 n (%)	1 (50)	0 (0)	2 (100)	3 (75)	4 (57)
	Diarrhea	Any n	0	0	1	1	5
		Day 0 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (20)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

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Table 14.3.1-2.6.2-3: Frequency of subjects with solicited systemic reactions by term per day - BNT162b2

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=16)	Total (N=96)
After boost	Diarrhea	Day 1 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (20)
		Day 2 n (%)	0 (0)	0 (0)	1 (100)	1 (100)	2 (40)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (20)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (40)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (20)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (20)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (20)
	Headache	Any n	2	5	8	15	35
		Day 0 n (%)	2 (100)	4 (80)	6 (75)	12 (80)	21 (60)
		Day 1 n (%)	1 (50)	3 (60)	5 (63)	9 (60)	22 (63)
		Day 2 n (%)	0 (0)	1 (20)	0 (0)	1 (7)	5 (14)
		Day 3 n (%)	1 (50)	0 (0)	0 (0)	1 (7)	1 (3)
		Day 4 n (%)	0 (0)	0 (0)	1 (13)	1 (7)	1 (3)
		Day 6 n (%)	1 (50)	1 (20)	0 (0)	2 (13)	3 (9)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (6)
	Fatigue	Any n	3	6	7	16	38
		Day 0 n (%)	3 (100)	4 (67)	5 (71)	12 (75)	25 (66)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 13 of 16)

Table 14.3.1-2.6.2-3: Frequency of subjects with solicited systemic reactions by term per day - BNT162b2

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=16)	Total (N=96)
After boost	Fatigue	Day 1 n (%)	2 (67)	5 (83)	5 (71)	12 (75)	27 (71)
		Day 2 n (%)	1 (33)	2 (33)	1 (14)	4 (25)	9 (24)
		Day 3 n (%)	0 (0)	1 (17)	0 (0)	1 (6)	3 (8)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (5)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (3)
	Myalgia	Any n	2	4	4	10	26
		Day 0 n (%)	1 (50)	4 (100)	1 (25)	6 (60)	13 (50)
		Day 1 n (%)	1 (50)	3 (75)	3 (75)	7 (70)	20 (77)
		Day 2 n (%)	0 (0)	1 (25)	0 (0)	1 (10)	5 (19)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (8)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (8)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (8)
		Day 6 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (4)
	Arthralgia	Any n	0	1	3	4	16
		Day 0 n (%)	0 (0)	1 (100)	1 (33)	2 (50)	6 (38)
		Day 1 n (%)	0 (0)	1 (100)	2 (67)	3 (75)	13 (81)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 14 of 16)

Table 14.3.1-2.6.2-3: Frequency of subjects with solicited systemic reactions by term per day - BNT162b2

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=16)	Total (N=96)
After boost	Arthralgia	Day 2 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	5 (31)
		Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (13)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (13)
		Day 5 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (6)
	Chills	Any n	0	1	4	5	17
		Day 0 n (%)	0 (0)	0 (0)	3 (75)	3 (60)	6 (35)
		Day 1 n (%)	0 (0)	1 (100)	4 (100)	5 (100)	14 (82)
	Loss of Appetite	Any n	1	1	3	5	9
		Day 0 n (%)	0 (0)	0 (0)	1 (33)	1 (20)	1 (11)
		Day 1 n (%)	0 (0)	0 (0)	3 (100)	3 (60)	6 (67)
		Day 2 n (%)	0 (0)	1 (100)	1 (33)	2 (40)	2 (22)
		Day 3 n (%)	1 (100)	1 (100)	0 (0)	2 (40)	2 (22)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (11)
	Malaise	Any n	2	1	5	8	23
		Day 0 n (%)	1 (50)	1 (100)	1 (20)	3 (38)	9 (39)
		Day 1 n (%)	1 (50)	0 (0)	5 (100)	6 (75)	16 (70)
		Day 2 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (4)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 15 of 16)

Table 14.3.1-2.6.2-3: Frequency of subjects with solicited systemic reactions by term per day - BNT162b2

Safety set

			Older dose ranging cohorts				
		Day after immunization	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=16)	Total (N=96)
After boost	Malaise	Day 3 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (4)
		Day 4 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (4)
		Day 7 n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (4)
	Fever	Any n	0	0	3	3	5
		Day 1 n (%)	0 (0)	0 (0)	3 (100)	3 (100)	5 (100)

The denominator for the percentage calculation is Any n.
N = number of subjects in the analysis set; n = number of subjects with data available; N/A = not available; - = not estimable.

Program: Tsaf_sysR_6.sas (Page 16 of 16)

14.3.1-3 Adverse events

Table 14.3.1-3.1.1-3: Summary of TEAEs - BNT162b2

Safety set

		Younger dose ranging cohorts					
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=60) n (%) E
Prime up to Day 7 after prime	Any TEAE	5 (42) 11	4 (33) 6	12 (100) 32	10 (83) 24	11 (92) 22	42 (70) 95
	Related TEAE	4 (33) 7	3 (25) 3	12 (100) 27	10 (83) 22	11 (92) 16	40 (67) 75
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Prime up to boost or Day 28 after prime (whatever comes first)	Any TEAE	6 (50) 12	6 (50) 11	12 (100) 38	10 (83) 24	11 (92) 24	45 (75) 109
	Related TEAE	4 (33) 7	3 (25) 3	12 (100) 27	10 (83) 22	11 (92) 16	40 (67) 75
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	0 (0) 0	0 (0) 0	1 (2) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_1.sas (Page 1 of 6)

Table 14.3.1-3.1.1-3: Summary of TEAEs - BNT162b2

Safety set

		Younger dose ranging cohorts					
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=60) n (%) E
Boost up to Day 7 after boost	Any TEAE	2 (17) 2	2 (17) 5	10 (83) 20	1 (8) 2	1 (8) 4	16 (27) 33
	Related TEAE	0 (0) 0	0 (0) 0	10 (83) 17	1 (8) 2	1 (8) 4	12 (20) 23
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Boost up to Day 28 after boost	Any TEAE	5 (42) 5	5 (42) 15	10 (83) 21	2 (17) 3	1 (8) 4	23 (38) 48
	Related TEAE	1 (8) 1	0 (0) 0	10 (83) 17	1 (8) 2	1 (8) 4	13 (22) 24
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_1.sas (Page 2 of 6)

Table 14.3.1-3.1.1-3: Summary of TEAEs - BNT162b2

Safety set

		Younger dose ranging cohorts					
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=60) n (%) E
Prime up to Day 28 after boost or after prime (if no boost)	Any TEAE	9 (75) 17	7 (58) 26	12 (100) 59	11 (92) 27	11 (92) 28	50 (83) 157
	Related TEAE	5 (42) 8	3 (25) 3	12 (100) 44	10 (83) 24	11 (92) 20	41 (68) 99
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	0 (0) 0	0 (0) 0	1 (2) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_1.sas (Page 3 of 6)

Table 14.3.1-3.1.1-3: Summary of TEAEs - BNT162b2

Safety set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=96) n (%) E
Prime up to Day 7 after prime	Any TEAE	2 (17) 6	2 (17) 3	2 (17) 4	6 (17) 13	48 (50) 108
	Related TEAE	2 (17) 3	0 (0) 0	1 (8) 1	3 (8) 4	43 (45) 79
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Prime up to boost or Day 28 after prime (whatever comes first)	Any TEAE	3 (25) 9	3 (25) 4	3 (25) 7	9 (25) 20	54 (56) 129
	Related TEAE	3 (25) 6	0 (0) 0	1 (8) 1	4 (11) 7	44 (46) 82
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	2 (17) 4	2 (6) 4	3 (3) 5
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_1.sas (Page 4 of 6)

Table 14.3.1-3.1.1-3: Summary of TEAEs - BNT162b2

Safety set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=96) n (%) E
Boost up to Day 7 after boost	Any TEAE	2 (17) 4	0 (0) 0	2 (17) 2	4 (11) 6	20 (21) 39
	Related TEAE	1 (8) 1	0 (0) 0	0 (0) 0	1 (3) 1	13 (14) 24
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Boost up to Day 28 after boost	Any TEAE	2 (17) 4	5 (42) 8	3 (25) 4	10 (28) 16	33 (34) 64
	Related TEAE	1 (8) 1	0 (0) 0	0 (0) 0	1 (3) 1	14 (15) 25
	Grade >=3 TEAE	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_1.sas (Page 5 of 6)

Table 14.3.1-3.1.1-3: Summary of TEAEs - BNT162b2

Safety set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=96) n (%) E
Prime up to Day 28 after boost or after prime (if no boost)	Any TEAE	3 (25) 13	7 (58) 12	4 (33) 11	14 (39) 36	64 (67) 193
	Related TEAE	3 (25) 7	0 (0) 0	1 (8) 1	4 (11) 8	45 (47) 107
	Grade >=3 TEAE	0 (0) 0	1 (8) 1	2 (17) 4	3 (8) 5	4 (4) 6
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Any TESAE	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_1.sas (Page 6 of 6)

Table 14.3.1-3.1.2-3: Summary of TEAEs - completers only - BNT162b2

Prime + 7 Days completers set

		Younger dose ranging cohorts					
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=60) n (%) E
Prime up to Day 7 after prime	Any TEAE	5 (42) 11	4 (33) 6	12 (100) 32	10 (83) 24	11 (92) 22	42 (70) 95
	Related TEAE	4 (33) 7	3 (25) 3	12 (100) 27	10 (83) 22	11 (92) 16	40 (67) 75
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_2.sas (Page 1 of 2)

Table 14.3.1-3.1.2-3: Summary of TEAEs - completers only - BNT162b2

Prime + 7 Days completers set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=96) n (%) E
Prime up to Day 7 after prime	Any TEAE	2 (17) 6	2 (17) 3	2 (17) 4	6 (17) 13	48 (50) 108
	Related TEAE	2 (17) 3	0 (0) 0	1 (8) 1	3 (8) 4	43 (45) 79
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_2.sas (Page 2 of 2)

Table 14.3.1-3.1.2-3: Summary of TEAEs - completers only - BNT162b2

Prime to Boost or Prime + 28 Days completers set

		Younger dose ranging cohorts					
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=11) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=59) n (%) E
Prime up to boost or Day 28 after prime (whatever comes first)	Any TEAE	6 (50) 12	6 (50) 11	11 (100) 33	10 (83) 24	11 (92) 24	44 (75) 104
	Related TEAE	4 (33) 7	3 (25) 3	11 (100) 25	10 (83) 22	11 (92) 16	39 (66) 73
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (9) 1	0 (0) 0	0 (0) 0	1 (2) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_2.sas (Page 1 of 2)

Table 14.3.1-3.1.2-3: Summary of TEAEs - completers only - BNT162b2

Prime to Boost or Prime + 28 Days completers set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=95) n (%) E
Prime up to boost or Day 28 after prime (whatever comes first)	Any TEAE	3 (25) 9	3 (25) 4	3 (25) 7	9 (25) 20	53 (56) 124
	Related TEAE	3 (25) 6	0 (0) 0	1 (8) 1	4 (11) 7	43 (45) 80
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	2 (17) 4	2 (6) 4	3 (3) 5
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_2.sas (Page 2 of 2)

Table 14.3.1-3.1.2-3: Summary of TEAEs - completers only - BNT162b2

Boost + 7 Days completers set

		Younger dose ranging cohorts					
Time interval		1 µg (N=11) n (%) E	3 µg (N=12) n (%) E	10 µg (N=11) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=58) n (%) E
Boost up to Day 7 after boost	Any TEAE	2 (18) 2	2 (17) 5	10 (91) 20	1 (8) 2	1 (8) 4	16 (28) 33
	Related TEAE	0 (0) 0	0 (0) 0	10 (91) 17	1 (8) 2	1 (8) 4	12 (21) 23
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_2.sas (Page 1 of 2)

Table 14.3.1-3.1.2-3: Summary of TEAEs - completers only - BNT162b2

Boost + 7 Days completers set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=94) n (%) E
Boost up to Day 7 after boost	Any TEAE	2 (17) 4	0 (0) 0	2 (17) 2	4 (11) 6	20 (21) 39
	Related TEAE	1 (8) 1	0 (0) 0	0 (0) 0	1 (3) 1	13 (14) 24
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_2.sas (Page 2 of 2)

Table 14.3.1-3.1.2-3: Summary of TEAEs - completers only - BNT162b2

Boost + 28 Days completers set

		Younger dose ranging cohorts					
Time interval		1 µg (N=11) n (%) E	3 µg (N=12) n (%) E	10 µg (N=11) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=58) n (%) E
Boost up to Day 28 after boost	Any TEAE	5 (45) 5	5 (42) 15	10 (91) 21	2 (17) 3	1 (8) 4	23 (40) 48
	Related TEAE	1 (9) 1	0 (0) 0	10 (91) 17	1 (8) 2	1 (8) 4	13 (22) 24
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_2.sas (Page 1 of 2)

Table 14.3.1-3.1.2-3: Summary of TEAEs - completers only - BNT162b2

Boost + 28 Days completers set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=94) n (%) E
Boost up to Day 28 after boost	Any TEAE	2 (17) 4	5 (42) 8	3 (25) 4	10 (28) 16	33 (35) 64
	Related TEAE	1 (8) 1	0 (0) 0	0 (0) 0	1 (3) 1	14 (15) 25
	Grade >=3 TEAE	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_2.sas (Page 2 of 2)

Table 14.3.1-3.1.2-3: Summary of TEAEs - completers only - BNT162b2

Prime or Boost + 28 Days completers set

		Younger dose ranging cohorts					
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=11) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=59) n (%) E
Prime up to Day 28 after boost or after prime (if no boost)	Any TEAE	9 (75) 17	7 (58) 26	11 (100) 54	11 (92) 27	11 (92) 28	49 (83) 152
	Related TEAE	5 (42) 8	3 (25) 3	11 (100) 42	10 (83) 24	11 (92) 20	40 (68) 97
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (9) 1	0 (0) 0	0 (0) 0	1 (2) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_2.sas (Page 1 of 2)

Table 14.3.1-3.1.2-3: Summary of TEAEs - completers only - BNT162b2

Prime or Boost + 28 Days completers set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=95) n (%) E
Prime up to Day 28 after boost or after prime (if no boost)	Any TEAE	3 (25) 13	7 (58) 12	4 (33) 11	14 (39) 36	63 (66) 188
	Related TEAE	3 (25) 7	0 (0) 0	1 (8) 1	4 (11) 8	44 (46) 105
	Grade >=3 TEAE	0 (0) 0	1 (8) 1	2 (17) 4	3 (8) 5	4 (4) 6
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Any TESAE	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_2.sas (Page 2 of 2)

Table 14.3.1-3.1.3-3: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b2

Safety set

		Younger dose ranging cohorts					
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=60) n (%) E
Prime up to Day 7 after prime	Any TEAE	1 (8) 2	4 (33) 5	2 (17) 2	1 (8) 1	3 (25) 4	11 (18) 14
	Related TEAE	0 (0) 0	2 (17) 2	0 (0) 0	0 (0) 0	0 (0) 0	2 (3) 2
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Prime up to boost or Day 28 after prime (whatever comes first)	Any TEAE	2 (17) 3	6 (50) 10	5 (42) 7	1 (8) 1	4 (33) 5	18 (30) 26
	Related TEAE	0 (0) 0	2 (17) 2	0 (0) 0	0 (0) 0	0 (0) 0	2 (3) 2
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	0 (0) 0	0 (0) 0	1 (2) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 1 of 6)

Table 14.3.1-3.1.3-3: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b2

Safety set

		Younger dose ranging cohorts					
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=60) n (%) E
Boost up to Day 7 after boost	Any TEAE	2 (17) 2	2 (17) 4	3 (25) 3	1 (8) 2	1 (8) 3	9 (15) 14
	Related TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (8) 2	1 (8) 3	3 (5) 6
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Boost up to Day 28 after boost	Any TEAE	4 (33) 4	5 (42) 12	4 (33) 4	1 (8) 2	1 (8) 3	15 (25) 25
	Related TEAE	1 (8) 1	0 (0) 0	1 (8) 1	1 (8) 2	1 (8) 3	4 (7) 7
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 2 of 6)

Table 14.3.1-3.1.3-3: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b2

Safety set

		Younger dose ranging cohorts					
Time interval		1 µg (N=12) n (%) E	3 µg (N=12) n (%) E	10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=60) n (%) E
Prime up to Day 28 after boost or after prime (if no boost)	Any TEAE	5 (42) 7	7 (58) 22	7 (58) 11	2 (17) 3	5 (42) 8	26 (43) 51
	Related TEAE	1 (8) 1	2 (17) 2	1 (8) 1	1 (8) 2	1 (8) 3	6 (10) 9
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	0 (0) 0	0 (0) 0	1 (2) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 3 of 6)

Table 14.3.1-3.1.3-3: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b2

Safety set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=96) n (%) E
Prime up to Day 7 after prime	Any TEAE	2 (17) 2	2 (17) 3	2 (17) 4	6 (17) 9	17 (18) 23
	Related TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	3 (3) 3
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Prime up to boost or Day 28 after prime (whatever comes first)	Any TEAE	3 (25) 5	2 (17) 3	3 (25) 5	8 (22) 13	26 (27) 39
	Related TEAE	1 (8) 3	0 (0) 0	1 (8) 1	2 (6) 4	4 (4) 6
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	2 (17) 2	2 (6) 2	3 (3) 3
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 4 of 6)

Table 14.3.1-3.1.3-3: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b2

Safety set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=96) n (%) E
Boost up to Day 7 after boost	Any TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	10 (10) 15
	Related TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	3 (3) 6
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Boost up to Day 28 after boost	Any TEAE	0 (0) 0	4 (33) 6	1 (8) 1	5 (14) 7	20 (21) 32
	Related TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	4 (4) 7
	Grade >=3 TEAE	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 5 of 6)

Table 14.3.1-3.1.3-3: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b2

Safety set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=96) n (%) E
Prime up to Day 28 after boost or after prime (if no boost)	Any TEAE	3 (25) 5	6 (50) 9	3 (25) 6	12 (33) 20	38 (40) 71
	Related TEAE	1 (8) 3	0 (0) 0	1 (8) 1	2 (6) 4	8 (8) 13
	Grade >=3 TEAE	0 (0) 0	1 (8) 1	2 (17) 2	3 (8) 3	4 (4) 4
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Any TESAE	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 6 of 6)

Table 14.3.1-3.1.3-3: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b2

Safety boost set

		Younger dose ranging cohorts					
Time interval		1 µg (N=11) n (%) E	3 µg (N=12) n (%) E	10 µg (N=11) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=58) n (%) E
Prime up to Day 7 after prime	Any TEAE	1 (9) 2	4 (33) 5	1 (9) 1	1 (8) 1	3 (25) 4	10 (17) 13
	Related TEAE	0 (0) 0	2 (17) 2	0 (0) 0	0 (0) 0	0 (0) 0	2 (3) 2
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Prime up to boost or Day 28 after prime (whatever comes first)	Any TEAE	2 (18) 3	6 (50) 10	4 (36) 5	1 (8) 1	4 (33) 5	17 (29) 24
	Related TEAE	0 (0) 0	2 (17) 2	0 (0) 0	0 (0) 0	0 (0) 0	2 (3) 2
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (9) 1	0 (0) 0	0 (0) 0	1 (2) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 1 of 6)

Table 14.3.1-3.1.3-3: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b2

Safety boost set

		Younger dose ranging cohorts					
Time interval		1 µg (N=11) n (%) E	3 µg (N=12) n (%) E	10 µg (N=11) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=58) n (%) E
Boost up to Day 7 after boost	Any TEAE	2 (18) 2	2 (17) 4	3 (27) 3	1 (8) 2	1 (8) 3	9 (16) 14
	Related TEAE	0 (0) 0	0 (0) 0	1 (9) 1	1 (8) 2	1 (8) 3	3 (5) 6
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Boost up to Day 28 after boost	Any TEAE	4 (36) 4	5 (42) 12	4 (36) 4	1 (8) 2	1 (8) 3	15 (26) 25
	Related TEAE	1 (9) 1	0 (0) 0	1 (9) 1	1 (8) 2	1 (8) 3	4 (7) 7
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 2 of 6)

Table 14.3.1-3.1.3-3: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b2

Safety boost set

		Younger dose ranging cohorts					
Time interval		1 µg (N=11) n (%) E	3 µg (N=12) n (%) E	10 µg (N=11) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=58) n (%) E
Prime up to Day 28 after boost or after prime (if no boost)	Any TEAE	5 (45) 7	7 (58) 22	6 (55) 9	2 (17) 3	5 (42) 8	25 (43) 49
	Related TEAE	1 (9) 1	2 (17) 2	1 (9) 1	1 (8) 2	1 (8) 3	6 (10) 9
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (9) 1	0 (0) 0	0 (0) 0	1 (2) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 3 of 6)

Table 14.3.1-3.1.3-3: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b2

Safety boost set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=94) n (%) E
Prime up to Day 7 after prime	Any TEAE	2 (17) 2	2 (17) 3	2 (17) 4	6 (17) 9	16 (17) 22
	Related TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	3 (3) 3
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Prime up to boost or Day 28 after prime (whatever comes first)	Any TEAE	3 (25) 5	2 (17) 3	3 (25) 5	8 (22) 13	25 (27) 37
	Related TEAE	1 (8) 3	0 (0) 0	1 (8) 1	2 (6) 4	4 (4) 6
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	2 (17) 2	2 (6) 2	3 (3) 3
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 4 of 6)

Table 14.3.1-3.1.3-3: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b2

Safety boost set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=94) n (%) E
Boost up to Day 7 after boost	Any TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	10 (11) 15
	Related TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	3 (3) 6
	Grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
Boost up to Day 28 after boost	Any TEAE	0 (0) 0	4 (33) 6	1 (8) 1	5 (14) 7	20 (21) 32
	Related TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	4 (4) 7
	Grade >=3 TEAE	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0
	Any TESAE	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 5 of 6)

Table 14.3.1-3.1.3-3: Summary of TEAEs without AEs based on solicited reporting via diaries - BNT162b2

Safety boost set

		Older dose ranging cohorts				
Time interval		10 µg (N=12) n (%) E	20 µg (N=12) n (%) E	30 µg (N=12) n (%) E	Total (N=36) n (%) E	Total (N=94) n (%) E
Prime up to Day 28 after boost or after prime (if no boost)	Any TEAE	3 (25) 5	6 (50) 9	3 (25) 6	12 (33) 20	37 (39) 69
	Related TEAE	1 (8) 3	0 (0) 0	1 (8) 1	2 (6) 4	8 (9) 13
	Grade >=3 TEAE	0 (0) 0	1 (8) 1	2 (17) 2	3 (8) 3	4 (4) 4
	Related grade >=3 TEAE	0 (0) 0	0 (0) 0	1 (8) 1	1 (3) 1	1 (1) 1
	Any TESAE	0 (0) 0	1 (8) 1	0 (0) 0	1 (3) 1	1 (1) 1
	Related TESAE	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0	0 (0) 0

The denominator for the percentage calculation is N.
E = number of events; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available;
TE(S)AE = treatment emergent (serious) adverse event.

Program: Tsaf_AE_1_4.sas (Page 6 of 6)

Table 14.3.1-3.1.4-3: Summary of TEAEs of special interest - BNT162b2

Safety set

No respective treatment emergent adverse events were recorded.

Table 14.3.1-3.1.4-3: Summary of TEAEs of special interest - BNT162b2

Safety boost set

No respective treatment emergent adverse events were recorded.

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Blood and lymphatic system disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
External ear inflammation	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	1 (8)	1 (8)	3 (25)	0 (0)	2 (17)	7 (12)
Abdominal discomfort	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Diarrhoea	1 (8)	0 (0)	1 (8)	0 (0)	2 (17)	4 (7)
Dyspepsia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nausea	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Toothache	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
General disorders and administration site conditions	4 (33)	1 (8)	12 (100)	10 (83)	11 (92)	38 (63)
Chest pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Fatigue	3 (25)	0 (0)	4 (33)	6 (50)	1 (8)	14 (23)
Influenza like illness	1 (8)	0 (0)	4 (33)	2 (17)	4 (33)	11 (18)
Injection site haematoma	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 1 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Injection site reaction	2 (17)	0 (0)	12 (100)	10 (83)	10 (83)	34 (57)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Vessel puncture site haematoma	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Infections and infestations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Gastroenteritis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Investigations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Amylase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
C-reactive protein increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Lipase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Arthralgia	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 2 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Musculoskeletal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Myalgia	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Tendon pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	0 (0)	0 (0)	4 (33)	2 (17)	2 (17)	8 (13)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	0 (0)	0 (0)	4 (33)	2 (17)	1 (8)	7 (12)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal colic	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 3 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Hot flush	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 4 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Blood and lymphatic system disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
External ear inflammation	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Eye disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Blepharitis	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	1 (8)	1 (8)	5 (42)	0 (0)	2 (17)	9 (15)
Abdominal discomfort	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	1 (8)	0 (0)	2 (17)	0 (0)	2 (17)	5 (8)
Dyspepsia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nausea	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Toothache	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (3)
General disorders and administration site conditions	4 (33)	1 (8)	12 (100)	10 (83)	11 (92)	38 (63)
Chest pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 5 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Fatigue	3 (25)	0 (0)	4 (33)	6 (50)	1 (8)	14 (23)
Influenza like illness	1 (8)	0 (0)	4 (33)	2 (17)	4 (33)	11 (18)
Injection site haematoma	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injection site reaction	2 (17)	0 (0)	12 (100)	10 (83)	10 (83)	34 (57)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Vessel puncture site haematoma	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Infections and infestations	1 (8)	0 (0)	2 (17)	0 (0)	1 (8)	4 (7)
Cestode infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Gastroenteritis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Nasopharyngitis	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Rhinitis	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 6 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Injury, poisoning and procedural complications	1 (8)	1 (8)	1 (8)	0 (0)	0 (0)	3 (5)
Arthropod sting	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Sunburn	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (3)
Investigations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Amylase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
C-reactive protein increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Lipase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	3 (25)	0 (0)	1 (8)	4 (7)
Arthralgia	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Myalgia	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
Neck pain	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Tendon pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	0 (0)	0 (0)	4 (33)	2 (17)	2 (17)	8 (13)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 7 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	0 (0)	0 (0)	4 (33)	2 (17)	1 (8)	7 (12)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal colic	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Seborrhoeic dermatitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Hot flush	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 8 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Boost up to Day 7 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
General disorders and administration site conditions	0 (0)	0 (0)	10 (83)	0 (0)	0 (0)	10 (17)
Axillary pain	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Fatigue	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Influenza like illness	0 (0)	0 (0)	4 (33)	0 (0)	0 (0)	4 (7)
Injection site reaction	0 (0)	0 (0)	10 (83)	0 (0)	0 (0)	10 (17)
Malaise	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Vessel puncture site pain	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Infections and infestations	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (3)
Oral herpes	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Tonsillitis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Injury, poisoning and procedural complications	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Animal bite	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Nervous system disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 9 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Boost up to Day 7 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	4 (7)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	4 (7)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 10 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Gastrointestinal disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Haemorrhoids thrombosed	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Toothache	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
General disorders and administration site conditions	1 (8)	1 (8)	10 (83)	0 (0)	0 (0)	12 (20)
Axillary pain	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Fatigue	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (3)
Influenza like illness	1 (8)	0 (0)	4 (33)	0 (0)	0 (0)	5 (8)
Injection site reaction	0 (0)	0 (0)	10 (83)	0 (0)	0 (0)	10 (17)
Malaise	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Infections and infestations	1 (8)	1 (8)	1 (8)	0 (0)	0 (0)	3 (5)
Nasopharyngitis	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 11 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Oral herpes	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Tonsillitis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Injury, poisoning and procedural complications	2 (17)	2 (17)	1 (8)	0 (0)	0 (0)	5 (8)
Animal bite	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Ankle fracture	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Face injury	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin abrasion	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
Sunburn	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (3)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Muscle spasms	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	1 (8)	1 (8)	0 (0)	1 (8)	0 (0)	3 (5)
Dizziness	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Headache	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	2 (3)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Sensory disturbance	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Reproductive system and breast disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Dysmenorrhoea	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	4 (7)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	4 (7)
Painful respiration	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 13 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Blood and lymphatic system disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
External ear inflammation	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Eye disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Blepharitis	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	1 (8)	2 (17)	5 (42)	0 (0)	2 (17)	10 (17)
Abdominal discomfort	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	1 (8)	0 (0)	2 (17)	0 (0)	2 (17)	5 (8)
Dyspepsia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Gastrointestinal disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Haemorrhoids thrombosed	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 14 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Nausea	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Toothache	0 (0)	2 (17)	1 (8)	0 (0)	0 (0)	3 (5)
General disorders and administration site conditions	5 (42)	2 (17)	12 (100)	10 (83)	11 (92)	40 (67)
Axillary pain	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Chest pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Fatigue	3 (25)	1 (8)	4 (33)	6 (50)	1 (8)	15 (25)
Influenza like illness	2 (17)	0 (0)	8 (67)	2 (17)	4 (33)	16 (27)
Injection site haematoma	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injection site reaction	2 (17)	0 (0)	12 (100)	10 (83)	10 (83)	34 (57)
Malaise	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Vessel puncture site haematoma	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 15 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Infections and infestations	1 (8)	1 (8)	3 (25)	0 (0)	1 (8)	6 (10)
Cestode infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Gastroenteritis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Nasopharyngitis	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (3)
Oral herpes	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Rhinitis	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Tonsillitis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Injury, poisoning and procedural complications	3 (25)	3 (25)	1 (8)	0 (0)	0 (0)	7 (12)
Animal bite	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Ankle fracture	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Arthropod sting	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Face injury	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin abrasion	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
Sunburn	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	3 (5)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 16 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Investigations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Amylase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
C-reactive protein increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Lipase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	3 (25)	0 (0)	1 (8)	4 (7)
Arthralgia	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Muscle spasms	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Myalgia	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
Neck pain	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Tendon pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	1 (8)	1 (8)	4 (33)	3 (25)	2 (17)	11 (18)
Dizziness	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Headache	0 (0)	1 (8)	4 (33)	3 (25)	1 (8)	9 (15)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 17 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Sensory disturbance	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal colic	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Reproductive system and breast disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Dysmenorrhoea	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	4 (7)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	4 (7)
Painful respiration	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Seborrhoeic dermatitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 18 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (3)
Hot flush	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 19 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
External ear inflammation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	1 (8)	0 (0)	1 (3)	8 (8)
Abdominal discomfort	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Dyspepsia	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Nausea	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Toothache	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	1 (8)	0 (0)	1 (8)	2 (6)	40 (42)
Chest pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	14 (15)
Influenza like illness	1 (8)	0 (0)	0 (0)	1 (3)	12 (13)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	34 (35)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastroenteritis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
Amylase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lipase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	2 (17)	0 (0)	1 (8)	3 (8)	5 (5)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Back pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 21 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Musculoskeletal pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tendon pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Nervous system disorders	2 (17)	0 (0)	1 (8)	3 (8)	11 (11)
Dizziness	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Headache	1 (8)	0 (0)	0 (0)	1 (3)	8 (8)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal colic	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 23 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
External ear inflammation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Blepharitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	1 (8)	1 (8)	2 (6)	11 (11)
Abdominal discomfort	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
Dyspepsia	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Nausea	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Toothache	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
General disorders and administration site conditions	2 (17)	0 (0)	1 (8)	3 (8)	41 (43)
Chest pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	14 (15)
Influenza like illness	1 (8)	0 (0)	0 (0)	1 (3)	12 (13)
Injection site haematoma	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Injection site pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	34 (35)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Cestode infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastroenteritis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 25 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Arthropod sting	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sunburn	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Investigations	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
Amylase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lipase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	2 (17)	0 (0)	2 (17)	4 (11)	8 (8)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Back pain	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
Musculoskeletal pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tendon pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Nervous system disorders	2 (17)	1 (8)	2 (17)	5 (14)	13 (14)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Dizziness	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Headache	1 (8)	1 (8)	1 (8)	3 (8)	10 (10)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal colic	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Seborrhoeic dermatitis	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 27 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	1 (8)	0 (0)	0 (0)	1 (3)	11 (11)
Axillary pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Fatigue	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	10 (10)
Malaise	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tonsillitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Animal bite	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	1 (8)	0 (0)	2 (17)	3 (8)	4 (4)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 28 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Dizziness	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Headache	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Hot flush	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	2 (17)	0 (0)	2 (6)	3 (3)
Gastrointestinal disorder	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Haemorrhoids thrombosed	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Toothache	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
General disorders and administration site conditions	1 (8)	0 (0)	0 (0)	1 (3)	13 (14)
Axillary pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Fatigue	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	10 (10)
Malaise	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tonsillitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	0 (0)	2 (17)	0 (0)	2 (6)	7 (7)
Animal bite	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ankle fracture	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Face injury	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin abrasion	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Sunburn	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Musculoskeletal and connective tissue disorders	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Muscle spasms	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Nervous system disorders	1 (8)	1 (8)	3 (25)	5 (14)	8 (8)
Dizziness	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Headache	0 (0)	1 (8)	2 (17)	3 (8)	5 (5)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Sensory disturbance	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	0 (0)	1 (3)	5 (5)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Painful respiration	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Hot flush	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 32 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
External ear inflammation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Blepharitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	3 (25)	1 (8)	4 (11)	14 (15)
Abdominal discomfort	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
Dyspepsia	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Gastrointestinal disorder	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Haemorrhoids thrombosed	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 33 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Nausea	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Toothache	0 (0)	1 (8)	0 (0)	1 (3)	4 (4)
General disorders and administration site conditions	3 (25)	0 (0)	1 (8)	4 (11)	44 (46)
Axillary pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Chest pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Fatigue	1 (8)	0 (0)	0 (0)	1 (3)	16 (17)
Influenza like illness	1 (8)	0 (0)	0 (0)	1 (3)	17 (18)
Injection site haematoma	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Injection site pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	34 (35)
Malaise	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
Cestode infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastroenteritis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tonsillitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	0 (0)	2 (17)	0 (0)	2 (6)	9 (9)
Animal bite	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ankle fracture	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Arthropod sting	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Face injury	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin abrasion	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Sunburn	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Investigations	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
Amylase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lipase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	2 (17)	1 (8)	2 (17)	5 (14)	9 (9)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Back pain	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
Muscle spasms	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tendon pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Nervous system disorders	2 (17)	2 (17)	4 (33)	8 (22)	19 (20)
Dizziness	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Headache	1 (8)	2 (17)	3 (25)	6 (17)	15 (16)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 36 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Sensory disturbance	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal colic	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	0 (0)	1 (3)	5 (5)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Painful respiration	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Seborrhoeic dermatitis	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 37 of 38)

Table 14.3.1-3.2.1-3: Frequency of subjects with TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
Hot flush	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_1.sas (Page 38 of 38)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Blood and lymphatic system disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Diarrhoea	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Nausea	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
General disorders and administration site conditions	4 (33)	0 (0)	12 (100)	10 (83)	11 (92)	37 (62)
Fatigue	3 (25)	0 (0)	4 (33)	5 (42)	1 (8)	13 (22)
Influenza like illness	1 (8)	0 (0)	4 (33)	2 (17)	4 (33)	11 (18)
Injection site reaction	2 (17)	0 (0)	12 (100)	10 (83)	10 (83)	34 (57)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Arthralgia	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Myalgia	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Nervous system disorders	0 (0)	0 (0)	2 (17)	2 (17)	1 (8)	5 (8)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	0 (0)	0 (0)	2 (17)	2 (17)	1 (8)	5 (8)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 1 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Hot flush	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 2 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Blood and lymphatic system disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Diarrhoea	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Nausea	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
General disorders and administration site conditions	4 (33)	0 (0)	12 (100)	10 (83)	11 (92)	37 (62)
Fatigue	3 (25)	0 (0)	4 (33)	5 (42)	1 (8)	13 (22)
Influenza like illness	1 (8)	0 (0)	4 (33)	2 (17)	4 (33)	11 (18)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injection site reaction	2 (17)	0 (0)	12 (100)	10 (83)	10 (83)	34 (57)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Arthralgia	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Myalgia	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Nervous system disorders	0 (0)	0 (0)	2 (17)	2 (17)	1 (8)	5 (8)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 3 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	0 (0)	0 (0)	2 (17)	2 (17)	1 (8)	5 (8)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Seborrhoeic dermatitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Hot flush	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 4 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety set

Boost up to Day 7 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
General disorders and administration site conditions	0 (0)	0 (0)	10 (83)	0 (0)	0 (0)	10 (17)
Axillary pain	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Influenza like illness	0 (0)	0 (0)	4 (33)	0 (0)	0 (0)	4 (7)
Injection site reaction	0 (0)	0 (0)	10 (83)	0 (0)	0 (0)	10 (17)
Infections and infestations	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Oral herpes	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 5 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
General disorders and administration site conditions	0 (0)	0 (0)	10 (83)	0 (0)	0 (0)	10 (17)
Axillary pain	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Influenza like illness	0 (0)	0 (0)	4 (33)	0 (0)	0 (0)	4 (7)
Injection site reaction	0 (0)	0 (0)	10 (83)	0 (0)	0 (0)	10 (17)
Infections and infestations	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Oral herpes	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Nervous system disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Sensory disturbance	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 6 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 7 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Blood and lymphatic system disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Gastrointestinal disorders	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Diarrhoea	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Nausea	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
General disorders and administration site conditions	4 (33)	0 (0)	12 (100)	10 (83)	11 (92)	37 (62)
Axillary pain	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Fatigue	3 (25)	0 (0)	4 (33)	5 (42)	1 (8)	13 (22)
Influenza like illness	1 (8)	0 (0)	8 (67)	2 (17)	4 (33)	15 (25)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injection site reaction	2 (17)	0 (0)	12 (100)	10 (83)	10 (83)	34 (57)
Infections and infestations	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 8 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Oral herpes	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Arthralgia	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Myalgia	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Nervous system disorders	1 (8)	0 (0)	2 (17)	2 (17)	1 (8)	6 (10)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	0 (0)	0 (0)	2 (17)	2 (17)	1 (8)	5 (8)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Sensory disturbance	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 9 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Seborrhoeic dermatitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (3)
Hot flush	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 10 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nausea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	1 (8)	0 (0)	0 (0)	1 (3)	38 (40)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	13 (14)
Influenza like illness	1 (8)	0 (0)	0 (0)	1 (3)	12 (13)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	34 (35)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	1 (8)	0 (0)	1 (8)	2 (6)	7 (7)
Dizziness	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 11 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nausea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	2 (17)	0 (0)	0 (0)	2 (6)	39 (41)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	13 (14)
Influenza like illness	1 (8)	0 (0)	0 (0)	1 (3)	12 (13)
Injection site haematoma	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Injection site pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	34 (35)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	1 (8)	0 (0)	1 (8)	2 (6)	7 (7)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 13 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Dizziness	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Seborrhoeic dermatitis	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 14 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	10 (10)
Axillary pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	10 (10)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Vascular disorders	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Hot flush	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 15 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	10 (10)
Axillary pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	10 (10)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sensory disturbance	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Vascular disorders	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Hot flush	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 17 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nausea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	2 (17)	0 (0)	0 (0)	2 (6)	39 (41)
Axillary pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	13 (14)
Influenza like illness	1 (8)	0 (0)	0 (0)	1 (3)	16 (17)
Injection site haematoma	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Injection site pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	34 (35)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	1 (8)	0 (0)	1 (8)	2 (6)	8 (8)
Dizziness	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Sensory disturbance	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Seborrhoeic dermatitis	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
Hot flush	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 20 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 7 after prime

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Blood and lymphatic system disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Diarrhoea	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Nausea	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
General disorders and administration site conditions	3 (27)	0 (0)	11 (100)	10 (83)	11 (92)	35 (60)
Fatigue	3 (27)	0 (0)	4 (36)	5 (42)	1 (8)	13 (22)
Influenza like illness	0 (0)	0 (0)	3 (27)	2 (17)	4 (33)	9 (16)
Injection site reaction	1 (9)	0 (0)	11 (100)	10 (83)	10 (83)	32 (55)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Arthralgia	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Myalgia	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Nervous system disorders	0 (0)	0 (0)	2 (18)	2 (17)	1 (8)	5 (9)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	0 (0)	0 (0)	2 (18)	2 (17)	1 (8)	5 (9)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 1 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 7 after prime

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Hot flush	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 2 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Blood and lymphatic system disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Diarrhoea	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Nausea	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
General disorders and administration site conditions	3 (27)	0 (0)	11 (100)	10 (83)	11 (92)	35 (60)
Fatigue	3 (27)	0 (0)	4 (36)	5 (42)	1 (8)	13 (22)
Influenza like illness	0 (0)	0 (0)	3 (27)	2 (17)	4 (33)	9 (16)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injection site reaction	1 (9)	0 (0)	11 (100)	10 (83)	10 (83)	32 (55)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Arthralgia	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Myalgia	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Nervous system disorders	0 (0)	0 (0)	2 (18)	2 (17)	1 (8)	5 (9)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 3 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	0 (0)	0 (0)	2 (18)	2 (17)	1 (8)	5 (9)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Seborrhoeic dermatitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Hot flush	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 4 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety boost set

Boost up to Day 7 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
General disorders and administration site conditions	0 (0)	0 (0)	10 (91)	0 (0)	0 (0)	10 (17)
Axillary pain	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Influenza like illness	0 (0)	0 (0)	4 (36)	0 (0)	0 (0)	4 (7)
Injection site reaction	0 (0)	0 (0)	10 (91)	0 (0)	0 (0)	10 (17)
Infections and infestations	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Oral herpes	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 5 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety boost set

Boost up to Day 28 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
General disorders and administration site conditions	0 (0)	0 (0)	10 (91)	0 (0)	0 (0)	10 (17)
Axillary pain	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Influenza like illness	0 (0)	0 (0)	4 (36)	0 (0)	0 (0)	4 (7)
Injection site reaction	0 (0)	0 (0)	10 (91)	0 (0)	0 (0)	10 (17)
Infections and infestations	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Oral herpes	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Nervous system disorders	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Sensory disturbance	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety boost set

Boost up to Day 28 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 7 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Blood and lymphatic system disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Gastrointestinal disorders	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Diarrhoea	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Nausea	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
General disorders and administration site conditions	3 (27)	0 (0)	11 (100)	10 (83)	11 (92)	35 (60)
Axillary pain	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Fatigue	3 (27)	0 (0)	4 (36)	5 (42)	1 (8)	13 (22)
Influenza like illness	0 (0)	0 (0)	7 (64)	2 (17)	4 (33)	13 (22)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injection site reaction	1 (9)	0 (0)	11 (100)	10 (83)	10 (83)	32 (55)
Infections and infestations	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 8 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Oral herpes	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Arthralgia	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Myalgia	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Nervous system disorders	1 (9)	0 (0)	2 (18)	2 (17)	1 (8)	6 (10)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	0 (0)	0 (0)	2 (18)	2 (17)	1 (8)	5 (9)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Sensory disturbance	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Seborrhoeic dermatitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (3)
Hot flush	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nausea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	1 (8)	0 (0)	0 (0)	1 (3)	36 (38)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	13 (14)
Influenza like illness	1 (8)	0 (0)	0 (0)	1 (3)	10 (11)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	32 (34)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	1 (8)	0 (0)	1 (8)	2 (6)	7 (7)
Dizziness	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nausea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	2 (17)	0 (0)	0 (0)	2 (6)	37 (39)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	13 (14)
Influenza like illness	1 (8)	0 (0)	0 (0)	1 (3)	10 (11)
Injection site haematoma	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Injection site pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	32 (34)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	1 (8)	0 (0)	1 (8)	2 (6)	7 (7)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Dizziness	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Seborrhoeic dermatitis	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety boost set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	10 (11)
Axillary pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	10 (11)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Vascular disorders	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Hot flush	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety boost set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	10 (11)
Axillary pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	10 (11)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sensory disturbance	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety boost set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Vascular disorders	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Hot flush	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 17 of 20)

Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nausea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	2 (17)	0 (0)	0 (0)	2 (6)	37 (39)
Axillary pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	13 (14)
Influenza like illness	1 (8)	0 (0)	0 (0)	1 (3)	14 (15)
Injection site haematoma	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Injection site pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	32 (34)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	1 (8)	0 (0)	1 (8)	2 (6)	8 (9)
Dizziness	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Sensory disturbance	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.2-3: Frequency of subjects with TEAEs related to IMP by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Seborrhoeic dermatitis	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
Hot flush	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_2.sas (Page 20 of 20)

Table 14.3.1-3.2.3-3: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 1 of 8)

Table 14.3.1-3.2.3-3: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Gastrointestinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Neck pain	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 2 of 8)

Table 14.3.1-3.2.3-3: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Face injury	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 3 of 8)

Table 14.3.1-3.2.3-3: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Gastrointestinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Face injury	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Neck pain	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 4 of 8)

Table 14.3.1-3.2.3-3: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Nervous system disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 5 of 8)

Table 14.3.1-3.2.3-3: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Gastrointestinal disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Abdominal pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Back pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Headache	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 6 of 8)

Table 14.3.1-3.2.3-3: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Injury, poisoning and procedural complications	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Face injury	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 7 of 8)

Table 14.3.1-3.2.3-3: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Gastrointestinal disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Abdominal pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Injury, poisoning and procedural complications	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Face injury	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Back pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Headache	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 8 of 8)

Table 14.3.1-3.2.3-3: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 7 after prime

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 1 of 8)

Table 14.3.1-3.2.3-3: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Gastrointestinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Neck pain	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 2 of 8)

Table 14.3.1-3.2.3-3: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b2

Safety boost set

Boost up to Day 28 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Face injury	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 3 of 8)

Table 14.3.1-3.2.3-3: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Gastrointestinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Face injury	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Neck pain	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 4 of 8)

Table 14.3.1-3.2.3-3: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Nervous system disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 5 of 8)

Table 14.3.1-3.2.3-3: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Gastrointestinal disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Abdominal pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Back pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Headache	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 6 of 8)

Table 14.3.1-3.2.3-3: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b2

Safety boost set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Injury, poisoning and procedural complications	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Face injury	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 7 of 8)

Table 14.3.1-3.2.3-3: Frequency of subjects with TEAEs of grade >=3 by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Gastrointestinal disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Abdominal pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Injury, poisoning and procedural complications	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Face injury	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Back pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
Headache	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_3.sas (Page 8 of 8)

Table 14.3.1-3.2.4-3: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 1 of 6)

Table 14.3.1-3.2.4-3: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 2 of 6)

Table 14.3.1-3.2.4-3: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 3 of 6)

Table 14.3.1-3.2.4-3: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Nervous system disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 4 of 6)

Table 14.3.1-3.2.4-3: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Nervous system disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 5 of 6)

Table 14.3.1-3.2.4-3: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Nervous system disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 6 of 6)

Table 14.3.1-3.2.4-3: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 7 after prime

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 1 of 6)

Table 14.3.1-3.2.4-3: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 2 of 6)

Table 14.3.1-3.2.4-3: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 3 of 6)

Table 14.3.1-3.2.4-3: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Nervous system disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 4 of 6)

Table 14.3.1-3.2.4-3: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Nervous system disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 5 of 6)

Table 14.3.1-3.2.4-3: Frequency of subjects with TEAEs of grade >=3 and related to IMP by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Nervous system disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_4.sas (Page 6 of 6)

Table 14.3.1-3.2.5-3: Frequency of subjects with serious TEAEs by SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Ankle fracture	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_5.sas (Page 1 of 4)

Table 14.3.1-3.2.5-3: Frequency of subjects with serious TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Ankle fracture	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_5.sas (Page 2 of 4)

Table 14.3.1-3.2.5-3: Frequency of subjects with serious TEAEs by SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Injury, poisoning and procedural complications	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Ankle fracture	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_5.sas (Page 3 of 4)

Table 14.3.1-3.2.5-3: Frequency of subjects with serious TEAEs by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Injury, poisoning and procedural complications	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Ankle fracture	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_5.sas (Page 4 of 4)

Table 14.3.1-3.2.5-3: Frequency of subjects with serious TEAEs by SOC and PT - BNT162b2

Safety boost set

Boost up to Day 28 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Ankle fracture	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_5.sas (Page 1 of 4)

Table 14.3.1-3.2.5-3: Frequency of subjects with serious TEAEs by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Ankle fracture	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_5.sas (Page 2 of 4)

Table 14.3.1-3.2.5-3: Frequency of subjects with serious TEAEs by SOC and PT - BNT162b2

Safety boost set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Injury, poisoning and procedural complications	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Ankle fracture	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.2.5-3: Frequency of subjects with serious TEAEs by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Injury, poisoning and procedural complications	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Ankle fracture	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_2_5.sas (Page 4 of 4)

Table 14.3.1-3.2.6-3: Frequency of subjects with serious TEAEs related to IMP by SOC and PT - BNT162b2

Safety set

No respective treatment emergent adverse events were recorded.

Table 14.3.1-3.2.6-3: Frequency of subjects with serious TEAEs related to IMP by SOC and PT - BNT162b2

Safety boost set

No respective treatment emergent adverse events were recorded.

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.1-3.2.7-3: Frequency of subjects with TEAEs with unresolved, fatal or unknown outcome by SOC and PT - BNT162b2

Safety set

No respective treatment emergent adverse events were recorded.

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.1-3.2.7-3: Frequency of subjects with TEAEs with unresolved, fatal or unknown outcome by SOC and PT - BNT162b2

Safety boost set

No respective treatment emergent adverse events were recorded.

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime + 7 Days completers set

Prime up to Day 7 after prime

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Blood and lymphatic system disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
External ear inflammation	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	1 (8)	1 (8)	3 (25)	0 (0)	2 (17)	7 (12)
Abdominal discomfort	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Diarrhoea	1 (8)	0 (0)	1 (8)	0 (0)	2 (17)	4 (7)
Dyspepsia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nausea	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Toothache	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
General disorders and administration site conditions	4 (33)	1 (8)	12 (100)	10 (83)	11 (92)	38 (63)
Chest pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Fatigue	3 (25)	0 (0)	4 (33)	6 (50)	1 (8)	14 (23)
Influenza like illness	1 (8)	0 (0)	4 (33)	2 (17)	4 (33)	11 (18)
Injection site haematoma	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 1 of 8)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime + 7 Days completers set

Prime up to Day 7 after prime

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Injection site reaction	2 (17)	0 (0)	12 (100)	10 (83)	10 (83)	34 (57)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Vessel puncture site haematoma	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Infections and infestations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Gastroenteritis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Investigations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Amylase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
C-reactive protein increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Lipase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Arthralgia	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 2 of 8)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime + 7 Days completers set

Prime up to Day 7 after prime

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Musculoskeletal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Myalgia	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Tendon pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	0 (0)	0 (0)	4 (33)	2 (17)	2 (17)	8 (13)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	0 (0)	0 (0)	4 (33)	2 (17)	1 (8)	7 (12)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal colic	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 3 of 8)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime + 7 Days completers set

Prime up to Day 7 after prime

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Hot flush	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 4 of 8)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime + 7 Days completers set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
External ear inflammation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	1 (8)	0 (0)	1 (3)	8 (8)
Abdominal discomfort	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Dyspepsia	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Nausea	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Toothache	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	1 (8)	0 (0)	1 (8)	2 (6)	40 (42)
Chest pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	14 (15)
Influenza like illness	1 (8)	0 (0)	0 (0)	1 (3)	12 (13)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime + 7 Days completers set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	34 (35)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastroenteritis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
Amylase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lipase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	2 (17)	0 (0)	1 (8)	3 (8)	5 (5)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Back pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 6 of 8)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime + 7 Days completers set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Musculoskeletal pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tendon pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Nervous system disorders	2 (17)	0 (0)	1 (8)	3 (8)	11 (11)
Dizziness	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Headache	1 (8)	0 (0)	0 (0)	1 (3)	8 (8)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal colic	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 7 of 8)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime + 7 Days completers set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 8 of 8)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime to Boost or Prime + 28 Days completers set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=59) n (%)
Blood and lymphatic system disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Eye disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Blepharitis	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	1 (8)	1 (8)	4 (36)	0 (0)	2 (17)	8 (14)
Abdominal discomfort	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	1 (8)	0 (0)	1 (9)	0 (0)	2 (17)	4 (7)
Dyspepsia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nausea	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Toothache	0 (0)	1 (8)	1 (9)	0 (0)	0 (0)	2 (3)
General disorders and administration site conditions	4 (33)	1 (8)	11 (100)	10 (83)	11 (92)	37 (63)
Chest pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Fatigue	3 (25)	0 (0)	4 (36)	6 (50)	1 (8)	14 (24)
Influenza like illness	1 (8)	0 (0)	3 (27)	2 (17)	4 (33)	10 (17)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 1 of 8)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime to Boost or Prime + 28 Days completers set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=59) n (%)
Injection site haematoma	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injection site reaction	2 (17)	0 (0)	11 (100)	10 (83)	10 (83)	33 (56)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Vessel puncture site haematoma	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Infections and infestations	1 (8)	0 (0)	1 (9)	0 (0)	1 (8)	3 (5)
Cestode infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Gastroenteritis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Rhinitis	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Injury, poisoning and procedural complications	1 (8)	1 (8)	1 (9)	0 (0)	0 (0)	3 (5)
Arthropod sting	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Sunburn	1 (8)	0 (0)	1 (9)	0 (0)	0 (0)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 2 of 8)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime to Boost or Prime + 28 Days completers set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=59) n (%)
Investigations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Amylase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
C-reactive protein increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Lipase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	3 (27)	0 (0)	1 (8)	4 (7)
Arthralgia	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Myalgia	0 (0)	0 (0)	1 (9)	0 (0)	1 (8)	2 (3)
Neck pain	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Tendon pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	0 (0)	0 (0)	4 (36)	2 (17)	2 (17)	8 (14)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	0 (0)	0 (0)	4 (36)	2 (17)	1 (8)	7 (12)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 3 of 8)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime to Boost or Prime + 28 Days completers set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=59) n (%)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal colic	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Seborrhoeic dermatitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Hot flush	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 4 of 8)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime to Boost or Prime + 28 Days completers set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=95) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Blepharitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	1 (8)	1 (8)	2 (6)	10 (11)
Abdominal discomfort	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Dyspepsia	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Nausea	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Toothache	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
General disorders and administration site conditions	2 (17)	0 (0)	1 (8)	3 (8)	40 (42)
Chest pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Fatigue	0 (0)	0 (0)	0 (0)	0 (0)	14 (15)
Influenza like illness	1 (8)	0 (0)	0 (0)	1 (3)	11 (12)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 5 of 8)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime to Boost or Prime + 28 Days completers set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=95) n (%)
Injection site haematoma	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Injection site pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	33 (35)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Cestode infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastroenteritis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Arthropod sting	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sunburn	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 6 of 8)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime to Boost or Prime + 28 Days completers set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=95) n (%)
Investigations	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
Amylase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lipase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	2 (17)	0 (0)	2 (17)	4 (11)	8 (8)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Back pain	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
Musculoskeletal pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tendon pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Nervous system disorders	2 (17)	1 (8)	2 (17)	5 (14)	13 (14)
Dizziness	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Headache	1 (8)	1 (8)	1 (8)	3 (8)	10 (11)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 7 of 8)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime to Boost or Prime + 28 Days completers set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=95) n (%)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal colic	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Seborrhoeic dermatitis	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 8 of 8)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Boost + 7 Days completers set

Boost up to Day 7 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
General disorders and administration site conditions	0 (0)	0 (0)	10 (91)	0 (0)	0 (0)	10 (17)
Axillary pain	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Fatigue	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Influenza like illness	0 (0)	0 (0)	4 (36)	0 (0)	0 (0)	4 (7)
Injection site reaction	0 (0)	0 (0)	10 (91)	0 (0)	0 (0)	10 (17)
Malaise	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Vessel puncture site pain	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Infections and infestations	1 (9)	0 (0)	1 (9)	0 (0)	0 (0)	2 (3)
Oral herpes	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Tonsillitis	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Injury, poisoning and procedural complications	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Animal bite	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Nervous system disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 1 of 4)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Boost + 7 Days completers set

Boost up to Day 7 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Dizziness	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	1 (9)	1 (8)	1 (8)	4 (7)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	1 (8)	1 (9)	1 (8)	1 (8)	4 (7)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 2 of 4)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Boost + 7 Days completers set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	1 (8)	0 (0)	0 (0)	1 (3)	11 (12)
Axillary pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Fatigue	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	10 (11)
Malaise	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tonsillitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Animal bite	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	1 (8)	0 (0)	2 (17)	3 (8)	4 (4)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 3 of 4)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Boost + 7 Days completers set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Dizziness	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Headache	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Hot flush	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 4 of 4)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Boost + 28 Days completers set

Boost up to Day 28 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Gastrointestinal disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Haemorrhoids thrombosed	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Toothache	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
General disorders and administration site conditions	1 (9)	1 (8)	10 (91)	0 (0)	0 (0)	12 (21)
Axillary pain	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Fatigue	0 (0)	1 (8)	1 (9)	0 (0)	0 (0)	2 (3)
Influenza like illness	1 (9)	0 (0)	4 (36)	0 (0)	0 (0)	5 (9)
Injection site reaction	0 (0)	0 (0)	10 (91)	0 (0)	0 (0)	10 (17)
Malaise	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Infections and infestations	1 (9)	1 (8)	1 (9)	0 (0)	0 (0)	3 (5)
Nasopharyngitis	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 1 of 6)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Boost + 28 Days completers set

Boost up to Day 28 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Oral herpes	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Tonsillitis	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Injury, poisoning and procedural complications	2 (18)	2 (17)	1 (9)	0 (0)	0 (0)	5 (9)
Animal bite	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Ankle fracture	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Face injury	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin abrasion	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
Sunburn	1 (9)	0 (0)	1 (9)	0 (0)	0 (0)	2 (3)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Muscle spasms	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	1 (9)	1 (8)	0 (0)	1 (8)	0 (0)	3 (5)
Dizziness	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Headache	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	2 (3)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Sensory disturbance	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 2 of 6)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Boost + 28 Days completers set

Boost up to Day 28 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Reproductive system and breast disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Dysmenorrhoea	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	1 (9)	1 (8)	1 (8)	4 (7)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	1 (8)	1 (9)	1 (8)	1 (8)	4 (7)
Painful respiration	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Hot flush	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 3 of 6)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Boost + 28 Days completers set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	2 (17)	0 (0)	2 (6)	3 (3)
Gastrointestinal disorder	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Haemorrhoids thrombosed	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Toothache	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
General disorders and administration site conditions	1 (8)	0 (0)	0 (0)	1 (3)	13 (14)
Axillary pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Fatigue	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
Influenza like illness	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	10 (11)
Malaise	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 4 of 6)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Boost + 28 Days completers set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tonsillitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	0 (0)	2 (17)	0 (0)	2 (6)	7 (7)
Animal bite	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ankle fracture	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Face injury	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin abrasion	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Sunburn	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Musculoskeletal and connective tissue disorders	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Muscle spasms	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Nervous system disorders	1 (8)	1 (8)	3 (25)	5 (14)	8 (9)
Dizziness	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Headache	0 (0)	1 (8)	2 (17)	3 (8)	5 (5)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Sensory disturbance	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 5 of 6)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Boost + 28 Days completers set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	0 (0)	1 (3)	5 (5)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Painful respiration	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Hot flush	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 6 of 6)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=59) n (%)
Blood and lymphatic system disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Eye disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Blepharitis	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	1 (8)	2 (17)	4 (36)	0 (0)	2 (17)	9 (15)
Abdominal discomfort	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Abdominal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	1 (8)	0 (0)	1 (9)	0 (0)	2 (17)	4 (7)
Dyspepsia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Gastrointestinal disorder	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Haemorrhoids thrombosed	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Nausea	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Toothache	0 (0)	2 (17)	1 (9)	0 (0)	0 (0)	3 (5)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 1 of 12)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=59) n (%)
General disorders and administration site conditions	5 (42)	2 (17)	11 (100)	10 (83)	11 (92)	39 (66)
Axillary pain	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Chest pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Fatigue	3 (25)	1 (8)	4 (36)	6 (50)	1 (8)	15 (25)
Influenza like illness	2 (17)	0 (0)	7 (64)	2 (17)	4 (33)	15 (25)
Injection site haematoma	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injection site reaction	2 (17)	0 (0)	11 (100)	10 (83)	10 (83)	33 (56)
Malaise	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Vessel puncture site haematoma	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	0 (0)	0 (0)	1 (9)	0 (0)	1 (8)	2 (3)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Infections and infestations	1 (8)	1 (8)	2 (18)	0 (0)	1 (8)	5 (8)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 2 of 12)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=59) n (%)
Cestode infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Gastroenteritis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Nasopharyngitis	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Oral herpes	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Rhinitis	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Tonsillitis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Injury, poisoning and procedural complications	3 (25)	3 (25)	1 (9)	0 (0)	0 (0)	7 (12)
Animal bite	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Ankle fracture	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Arthropod sting	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Face injury	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin abrasion	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
Sunburn	2 (17)	0 (0)	1 (9)	0 (0)	0 (0)	3 (5)
Investigations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Amylase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=59) n (%)
C-reactive protein increased	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Lipase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	3 (27)	0 (0)	1 (8)	4 (7)
Arthralgia	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Muscle spasms	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Myalgia	0 (0)	0 (0)	1 (9)	0 (0)	1 (8)	2 (3)
Neck pain	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Tendon pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	1 (8)	1 (8)	4 (36)	3 (25)	2 (17)	11 (19)
Dizziness	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Headache	0 (0)	1 (8)	4 (36)	3 (25)	1 (8)	9 (15)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 4 of 12)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=59) n (%)
Sensory disturbance	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal colic	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Reproductive system and breast disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Dysmenorrhoea	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	1 (9)	1 (8)	1 (8)	4 (7)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	1 (8)	1 (9)	1 (8)	1 (8)	4 (7)
Painful respiration	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Seborrhoeic dermatitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 5 of 12)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=59) n (%)
Hot flush	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 6 of 12)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=95) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Blepharitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	3 (25)	1 (8)	4 (11)	13 (14)
Abdominal discomfort	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Dyspepsia	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Gastrointestinal disorder	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Haemorrhoids thrombosed	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nausea	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Toothache	0 (0)	1 (8)	0 (0)	1 (3)	4 (4)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 7 of 12)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=95) n (%)
General disorders and administration site conditions	3 (25)	0 (0)	1 (8)	4 (11)	43 (45)
Axillary pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Chest pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Fatigue	1 (8)	0 (0)	0 (0)	1 (3)	16 (17)
Influenza like illness	1 (8)	0 (0)	0 (0)	1 (3)	16 (17)
Injection site haematoma	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Injection site pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Injection site reaction	0 (0)	0 (0)	0 (0)	0 (0)	33 (35)
Malaise	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 8 of 12)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=95) n (%)
Cestode infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastroenteritis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tonsillitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	0 (0)	2 (17)	0 (0)	2 (6)	9 (9)
Animal bite	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ankle fracture	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Arthropod sting	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Face injury	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin abrasion	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Sunburn	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Investigations	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
Amylase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 9 of 12)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=95) n (%)
C-reactive protein increased	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lipase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	2 (17)	1 (8)	2 (17)	5 (14)	9 (9)
Arthralgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Back pain	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
Muscle spasms	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Myalgia	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tendon pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Nervous system disorders	2 (17)	2 (17)	4 (33)	8 (22)	19 (20)
Dizziness	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Headache	1 (8)	2 (17)	3 (25)	6 (17)	15 (16)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 10 of 12)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=95) n (%)
Sensory disturbance	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal colic	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	0 (0)	1 (3)	5 (5)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Painful respiration	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Seborrhoeic dermatitis	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 11 of 12)

Table 14.3.1-3.3.1-3: Frequency of subjects with TEAEs by SOC and PT - completers only - BNT162b2

Prime or Boost + 28 Days completers set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=95) n (%)
Hot flush	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_3_1.sas (Page 12 of 12)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Blood and lymphatic system disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
External ear inflammation	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	2 (3)
Abdominal discomfort	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Dyspepsia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Toothache	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
General disorders and administration site conditions	0 (0)	1 (8)	1 (8)	1 (8)	3 (25)	6 (10)
Chest pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injection site haematoma	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Vessel puncture site haematoma	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 1 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Infections and infestations	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Gastroenteritis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Amylase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Lipase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Tendon pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal colic	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 2 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 3 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Blood and lymphatic system disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
External ear inflammation	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Eye disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Blepharitis	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	1 (8)	1 (8)	1 (8)	0 (0)	0 (0)	3 (5)
Abdominal discomfort	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Dyspepsia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Toothache	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (3)
General disorders and administration site conditions	0 (0)	1 (8)	1 (8)	1 (8)	3 (25)	6 (10)
Chest pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injection site haematoma	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 4 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Vessel puncture site haematoma	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Infections and infestations	1 (8)	0 (0)	2 (17)	0 (0)	1 (8)	4 (7)
Cestode infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Gastroenteritis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Nasopharyngitis	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Rhinitis	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Injury, poisoning and procedural complications	1 (8)	1 (8)	1 (8)	0 (0)	0 (0)	3 (5)
Arthropod sting	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Sunburn	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (3)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Amylase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Lipase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 5 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Neck pain	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Tendon pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal colic	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Seborrhoeic dermatitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 6 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Boost up to Day 7 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
General disorders and administration site conditions	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Infections and infestations	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (3)
Oral herpes	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Tonsillitis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Injury, poisoning and procedural complications	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Animal bite	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	4 (7)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 7 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Boost up to Day 7 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Oropharyngeal pain	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	4 (7)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 8 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Gastrointestinal disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Haemorrhoids thrombosed	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Toothache	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
General disorders and administration site conditions	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (3)
Malaise	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Infections and infestations	1 (8)	1 (8)	1 (8)	0 (0)	0 (0)	3 (5)
Nasopharyngitis	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Oral herpes	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Tonsillitis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Injury, poisoning and procedural complications	2 (17)	2 (17)	1 (8)	0 (0)	0 (0)	5 (8)
Animal bite	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Ankle fracture	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 9 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Face injury	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin abrasion	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
Sunburn	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (3)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Muscle spasms	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Sensory disturbance	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Reproductive system and breast disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Dysmenorrhoea	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	4 (7)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	4 (7)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 10 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Painful respiration	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 11 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Blood and lymphatic system disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Ear and labyrinth disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
External ear inflammation	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Eye disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Blepharitis	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	1 (8)	2 (17)	1 (8)	0 (0)	0 (0)	4 (7)
Abdominal discomfort	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Dyspepsia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Haemorrhoids thrombosed	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Toothache	0 (0)	2 (17)	1 (8)	0 (0)	0 (0)	3 (5)
General disorders and administration site conditions	0 (0)	2 (17)	2 (17)	1 (8)	3 (25)	8 (13)
Chest pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 12 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Injection site haematoma	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Malaise	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Vessel puncture site haematoma	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Infections and infestations	1 (8)	1 (8)	3 (25)	0 (0)	1 (8)	6 (10)
Cestode infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Gastroenteritis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Nasopharyngitis	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (3)
Oral herpes	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Rhinitis	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Tonsillitis	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 13 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Injury, poisoning and procedural complications	3 (25)	3 (25)	1 (8)	0 (0)	0 (0)	7 (12)
Animal bite	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Ankle fracture	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Arthropod sting	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Face injury	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin abrasion	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
Sunburn	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	3 (5)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Amylase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Lipase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Muscle spasms	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Neck pain	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 14 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Tendon pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (3)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Sensory disturbance	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal colic	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Reproductive system and breast disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Dysmenorrhoea	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	4 (7)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	4 (7)
Painful respiration	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 15 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Seborrhoeic dermatitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 16 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
External ear inflammation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
Abdominal discomfort	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspepsia	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Toothache	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	1 (8)	1 (3)	7 (7)
Chest pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 17 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastroenteritis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Amylase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Lipase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	2 (17)	0 (0)	1 (8)	3 (8)	3 (3)
Back pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Musculoskeletal pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Tendon pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Nervous system disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal colic	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 18 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 19 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
External ear inflammation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Blepharitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	1 (8)	0 (0)	1 (3)	4 (4)
Abdominal discomfort	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspepsia	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Toothache	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
General disorders and administration site conditions	1 (8)	0 (0)	1 (8)	2 (6)	8 (8)
Chest pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Injection site haematoma	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Injection site pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 20 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Cestode infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastroenteritis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Arthropod sting	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sunburn	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Investigations	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Amylase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Lipase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 21 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Musculoskeletal and connective tissue disorders	2 (17)	0 (0)	2 (17)	4 (11)	5 (5)
Back pain	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
Musculoskeletal pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tendon pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Nervous system disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal colic	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Seborrhoeic dermatitis	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 22 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tonsillitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Animal bite	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 23 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 24 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
Haemorrhoids thrombosed	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Toothache	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Malaise	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tonsillitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	0 (0)	2 (17)	0 (0)	2 (6)	7 (7)
Animal bite	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ankle fracture	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 25 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Face injury	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin abrasion	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Sunburn	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Musculoskeletal and connective tissue disorders	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Muscle spasms	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Nervous system disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Sensory disturbance	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	0 (0)	1 (3)	5 (5)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Painful respiration	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 27 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
External ear inflammation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Blepharitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	2 (17)	0 (0)	2 (6)	6 (6)
Abdominal discomfort	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspepsia	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Haemorrhoids thrombosed	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Toothache	0 (0)	1 (8)	0 (0)	1 (3)	4 (4)
General disorders and administration site conditions	1 (8)	0 (0)	1 (8)	2 (6)	10 (10)
Chest pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Injection site haematoma	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Injection site pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Malaise	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
Cestode infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastroenteritis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tonsillitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 29 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Injury, poisoning and procedural complications	0 (0)	2 (17)	0 (0)	2 (6)	9 (9)
Animal bite	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ankle fracture	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Arthropod sting	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Face injury	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin abrasion	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Sunburn	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Investigations	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Amylase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Lipase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	2 (17)	1 (8)	2 (17)	5 (14)	6 (6)
Back pain	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
Muscle spasms	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 30 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Tendon pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Nervous system disorders	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Sensory disturbance	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal colic	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	0 (0)	1 (3)	5 (5)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Painful respiration	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 31 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Seborrhoeic dermatitis	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 32 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 7 after prime

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Blood and lymphatic system disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	1 (9)	1 (8)	0 (0)	0 (0)	0 (0)	2 (3)
Abdominal discomfort	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Dyspepsia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Toothache	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
General disorders and administration site conditions	0 (0)	1 (8)	1 (9)	1 (8)	3 (25)	6 (10)
Chest pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injection site haematoma	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Vessel puncture site haematoma	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Infections and infestations	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 1 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 7 after prime

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Gastroenteritis	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Amylase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Lipase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Tendon pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal colic	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 2 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 7 after prime

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 3 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Blood and lymphatic system disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Eye disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Blepharitis	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	1 (9)	1 (8)	1 (9)	0 (0)	0 (0)	3 (5)
Abdominal discomfort	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Dyspepsia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Toothache	0 (0)	1 (8)	1 (9)	0 (0)	0 (0)	2 (3)
General disorders and administration site conditions	0 (0)	1 (8)	1 (9)	1 (8)	3 (25)	6 (10)
Chest pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injection site haematoma	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Vessel puncture site haematoma	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 4 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Infections and infestations	1 (9)	0 (0)	1 (9)	0 (0)	1 (8)	3 (5)
Cestode infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Gastroenteritis	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Rhinitis	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Injury, poisoning and procedural complications	1 (9)	1 (8)	1 (9)	0 (0)	0 (0)	3 (5)
Arthropod sting	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Sunburn	1 (9)	0 (0)	1 (9)	0 (0)	0 (0)	2 (3)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Amylase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Lipase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 5 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Neck pain	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Tendon pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal colic	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Seborrhoeic dermatitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 6 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Boost up to Day 7 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
General disorders and administration site conditions	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Infections and infestations	1 (9)	0 (0)	1 (9)	0 (0)	0 (0)	2 (3)
Oral herpes	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Tonsillitis	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Injury, poisoning and procedural complications	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Animal bite	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Nervous system disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	1 (9)	1 (8)	1 (8)	4 (7)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 7 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Boost up to Day 7 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Oropharyngeal pain	0 (0)	1 (8)	1 (9)	1 (8)	1 (8)	4 (7)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 8 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Boost up to Day 28 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Gastrointestinal disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Haemorrhoids thrombosed	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Toothache	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
General disorders and administration site conditions	0 (0)	1 (8)	1 (9)	0 (0)	0 (0)	2 (3)
Malaise	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Infections and infestations	1 (9)	1 (8)	1 (9)	0 (0)	0 (0)	3 (5)
Nasopharyngitis	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Oral herpes	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Tonsillitis	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Injury, poisoning and procedural complications	2 (18)	2 (17)	1 (9)	0 (0)	0 (0)	5 (9)
Animal bite	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Ankle fracture	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 9 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Boost up to Day 28 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Face injury	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin abrasion	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
Sunburn	1 (9)	0 (0)	1 (9)	0 (0)	0 (0)	2 (3)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Muscle spasms	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Sensory disturbance	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Reproductive system and breast disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Dysmenorrhoea	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	1 (9)	1 (8)	1 (8)	4 (7)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	1 (8)	1 (9)	1 (8)	1 (8)	4 (7)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Boost up to Day 28 after boost

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Painful respiration	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 11 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Blood and lymphatic system disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Eye disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Blepharitis	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	1 (9)	2 (17)	1 (9)	0 (0)	0 (0)	4 (7)
Abdominal discomfort	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Dyspepsia	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Haemorrhoids thrombosed	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Toothache	0 (0)	2 (17)	1 (9)	0 (0)	0 (0)	3 (5)
General disorders and administration site conditions	0 (0)	2 (17)	2 (18)	1 (8)	3 (25)	8 (14)
Chest pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injection site haematoma	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Injection site pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 12 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Malaise	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Vessel puncture site haematoma	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	0 (0)	0 (0)	1 (9)	0 (0)	1 (8)	2 (3)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Infections and infestations	1 (9)	1 (8)	2 (18)	0 (0)	1 (8)	5 (9)
Cestode infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Gastroenteritis	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Nasopharyngitis	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Oral herpes	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Rhinitis	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Tonsillitis	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Injury, poisoning and procedural complications	3 (27)	3 (25)	1 (9)	0 (0)	0 (0)	7 (12)
Animal bite	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 13 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Ankle fracture	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Arthropod sting	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Face injury	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin abrasion	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
Sunburn	2 (18)	0 (0)	1 (9)	0 (0)	0 (0)	3 (5)
Investigations	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Amylase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Lipase increased	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Back pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Muscle spasms	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Neck pain	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Tendon pain	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	1 (9)	0 (0)	0 (0)	0 (0)	1 (8)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 14 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Orthostatic intolerance	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Sensory disturbance	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal colic	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Reproductive system and breast disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Dysmenorrhoea	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	1 (9)	1 (8)	1 (8)	4 (7)
Nasal congestion	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	0 (0)	1 (8)	1 (9)	1 (8)	1 (8)	4 (7)
Painful respiration	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin and subcutaneous tissue disorders	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Seborrhoeic dermatitis	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Younger dose ranging cohorts					
System organ class Preferred term	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Skin irritation	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
Abdominal discomfort	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspepsia	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Toothache	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	1 (8)	1 (3)	7 (7)
Chest pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Injection site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Gastroenteritis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Amylase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Lipase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	2 (17)	0 (0)	1 (8)	3 (8)	3 (3)
Back pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Musculoskeletal pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Tendon pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Nervous system disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal colic	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 7 after prime

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Blepharitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	1 (8)	0 (0)	1 (3)	4 (4)
Abdominal discomfort	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspepsia	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Toothache	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
General disorders and administration site conditions	1 (8)	0 (0)	1 (8)	2 (6)	8 (9)
Chest pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Injection site haematoma	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Injection site pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 20 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Cestode infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastroenteritis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Arthropod sting	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sunburn	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Investigations	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Amylase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Lipase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	2 (17)	0 (0)	2 (17)	4 (11)	5 (5)
Back pain	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
Musculoskeletal pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tendon pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Nervous system disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal colic	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Seborrhoeic dermatitis	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tonsillitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Animal bite	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Boost up to Day 7 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 24 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
Haemorrhoids thrombosed	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Toothache	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
General disorders and administration site conditions	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Malaise	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tonsillitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	0 (0)	2 (17)	0 (0)	2 (6)	7 (7)
Animal bite	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ankle fracture	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 25 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Face injury	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin abrasion	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Sunburn	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Musculoskeletal and connective tissue disorders	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Muscle spasms	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Nervous system disorders	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Sensory disturbance	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	0 (0)	1 (3)	5 (5)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 26 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Boost up to Day 28 after boost

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Painful respiration	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin and subcutaneous tissue disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 27 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Blood and lymphatic system disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Blepharitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	0 (0)	2 (17)	0 (0)	2 (6)	6 (6)
Abdominal discomfort	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dyspepsia	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Haemorrhoids thrombosed	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Toothache	0 (0)	1 (8)	0 (0)	1 (3)	4 (4)
General disorders and administration site conditions	1 (8)	0 (0)	1 (8)	2 (6)	10 (11)
Chest pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Injection site haematoma	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Injection site pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Malaise	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Non-cardiac chest pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site erythema	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site haematoma	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Vessel puncture site swelling	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
Cestode infection	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastroenteritis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oral herpes	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tonsillitis	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	0 (0)	2 (17)	0 (0)	2 (6)	9 (10)
Animal bite	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 29 of 32)

Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Ankle fracture	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Arthropod sting	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Face injury	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin abrasion	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Sunburn	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Investigations	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Amylase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Lipase increased	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	2 (17)	1 (8)	2 (17)	5 (14)	6 (6)
Back pain	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
Muscle spasms	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal pain	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Neck pain	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tendon pain	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Nervous system disorders	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Hypoaesthesia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Orthostatic intolerance	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Sensory disturbance	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal colic	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Reproductive system and breast disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysmenorrhoea	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	0 (0)	1 (8)	0 (0)	1 (3)	5 (5)
Nasal congestion	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Painful respiration	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin and subcutaneous tissue disorders	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Seborrhoeic dermatitis	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.4.1-3: Frequency of subjects with TEAEs without AEs based on solicited reporting via diaries by SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

	Older dose ranging cohorts				
System organ class Preferred term	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Skin irritation	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_4_1.sas (Page 32 of 32)

Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Blood and lymphatic system disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
External ear inflammation	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	Any	1 (8)	1 (8)	3 (25)	0 (0)	2 (17)	7 (12)
Abdominal discomfort	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Diarrhoea	Mild	1 (8)	0 (0)	1 (8)	0 (0)	2 (17)	4 (7)
Dyspepsia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nausea	Mild	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Toothache	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
General disorders and administration site conditions	Any	4 (33)	1 (8)	12 (100)	10 (83)	11 (92)	38 (63)
Chest pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Fatigue	Mild	3 (25)	0 (0)	4 (33)	6 (50)	1 (8)	14 (23)
Influenza like illness	Mild	1 (8)	0 (0)	4 (33)	0 (0)	3 (25)	8 (13)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_5_1.sas (Page 1 of 46)

Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Influenza like illness	Moderate	0 (0)	0 (0)	0 (0)	2 (17)	1 (8)	3 (5)
Injection site haematoma	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Injection site reaction	Mild	2 (17)	0 (0)	7 (58)	9 (75)	10 (83)	28 (47)
	Moderate	0 (0)	0 (0)	5 (42)	1 (8)	0 (0)	6 (10)
Non-cardiac chest pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site erythema	Mild	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Vessel puncture site haematoma	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site swelling	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Infections and infestations	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Gastroenteritis	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Investigations	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Amylase increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
C-reactive protein increased	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_5_1.sas (Page 2 of 46)

Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Lipase increased	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	Any	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Arthralgia	Mild	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Back pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Myalgia	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Tendon pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	Any	0 (0)	0 (0)	4 (33)	2 (17)	2 (17)	8 (13)
Dizziness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	Mild	0 (0)	0 (0)	3 (25)	1 (8)	1 (8)	5 (8)
	Moderate	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (3)
Hypoaesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Orthostatic intolerance	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Renal colic	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Oropharyngeal pain	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin and subcutaneous tissue disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin irritation	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Hot flush	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Blood and lymphatic system disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
External ear inflammation	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Eye disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Blepharitis	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	Any	1 (8)	1 (8)	5 (42)	0 (0)	2 (17)	9 (15)
Abdominal discomfort	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Abdominal pain	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	Mild	1 (8)	0 (0)	2 (17)	0 (0)	2 (17)	5 (8)
Dyspepsia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nausea	Mild	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Toothache	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
General disorders and administration site conditions	Any	4 (33)	1 (8)	12 (100)	10 (83)	11 (92)	38 (63)
Chest pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Fatigue	Mild	3 (25)	0 (0)	4 (33)	6 (50)	1 (8)	14 (23)
Influenza like illness	Mild	1 (8)	0 (0)	4 (33)	0 (0)	3 (25)	8 (13)
	Moderate	0 (0)	0 (0)	0 (0)	2 (17)	1 (8)	3 (5)
Injection site haematoma	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Injection site pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injection site reaction	Mild	2 (17)	0 (0)	7 (58)	9 (75)	10 (83)	28 (47)
	Moderate	0 (0)	0 (0)	5 (42)	1 (8)	0 (0)	6 (10)
Non-cardiac chest pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site erythema	Mild	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Vessel puncture site haematoma	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site swelling	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Infections and infestations	Any	1 (8)	0 (0)	2 (17)	0 (0)	1 (8)	4 (7)
Cestode infection	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Gastroenteritis	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Nasopharyngitis	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Rhinitis	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Injury, poisoning and procedural complications	Any	1 (8)	1 (8)	1 (8)	0 (0)	0 (0)	3 (5)
Arthropod sting	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Sunburn	Mild	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (3)
Investigations	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Amylase increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
C-reactive protein increased	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Lipase increased	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	Any	0 (0)	0 (0)	3 (25)	0 (0)	1 (8)	4 (7)
Arthralgia	Mild	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Back pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Myalgia	Mild	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
Neck pain	Severe	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Tendon pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	Any	0 (0)	0 (0)	4 (33)	2 (17)	2 (17)	8 (13)
Dizziness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	Mild	0 (0)	0 (0)	3 (25)	1 (8)	1 (8)	5 (8)
	Moderate	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (3)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Hypoaesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Orthostatic intolerance	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Renal colic	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Oropharyngeal pain	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin and subcutaneous tissue disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Seborrhoeic dermatitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin irritation	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Hot flush	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Boost up to Day 7 after boost

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Cardiac disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
General disorders and administration site conditions	Any	0 (0)	0 (0)	10 (83)	0 (0)	0 (0)	10 (17)
Axillary pain	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Fatigue	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Influenza like illness	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
	Moderate	0 (0)	0 (0)	3 (25)	0 (0)	0 (0)	3 (5)
Injection site reaction	Mild	0 (0)	0 (0)	7 (58)	0 (0)	0 (0)	7 (12)
	Moderate	0 (0)	0 (0)	3 (25)	0 (0)	0 (0)	3 (5)
Malaise	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Vessel puncture site pain	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Infections and infestations	Any	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (3)
Oral herpes	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Boost up to Day 7 after boost

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Tonsillitis	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Injury, poisoning and procedural complications	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Animal bite	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Nervous system disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Dizziness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Orthostatic intolerance	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	4 (7)
Nasal congestion	Mild	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	Mild	0 (0)	1 (8)	1 (8)	1 (8)	0 (0)	3 (5)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Boost up to Day 7 after boost

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Skin and subcutaneous tissue disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin irritation	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Hot flush	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Cardiac disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Gastrointestinal disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorder	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Haemorrhoids thrombosed	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Toothache	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
General disorders and administration site conditions	Any	1 (8)	1 (8)	10 (83)	0 (0)	0 (0)	12 (20)
Axillary pain	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Fatigue	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Influenza like illness	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
	Moderate	1 (8)	0 (0)	3 (25)	0 (0)	0 (0)	4 (7)
Injection site reaction	Mild	0 (0)	0 (0)	7 (58)	0 (0)	0 (0)	7 (12)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Injection site reaction	Moderate	0 (0)	0 (0)	3 (25)	0 (0)	0 (0)	3 (5)
Malaise	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Infections and infestations	Any	1 (8)	1 (8)	1 (8)	0 (0)	0 (0)	3 (5)
Nasopharyngitis	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Oral herpes	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Tonsillitis	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Injury, poisoning and procedural complications	Any	2 (17)	2 (17)	1 (8)	0 (0)	0 (0)	5 (8)
Animal bite	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Ankle fracture	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Face injury	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin abrasion	Mild	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
Sunburn	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Sunburn	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Musculoskeletal and connective tissue disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Muscle spasms	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	Any	1 (8)	1 (8)	0 (0)	1 (8)	0 (0)	3 (5)
Dizziness	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Headache	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
	Moderate	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Orthostatic intolerance	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Sensory disturbance	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Reproductive system and breast disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Dysmenorrhoea	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	4 (7)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Nasal congestion	Mild	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	Mild	0 (0)	1 (8)	1 (8)	1 (8)	0 (0)	3 (5)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Painful respiration	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin and subcutaneous tissue disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin irritation	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Hot flush	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Blood and lymphatic system disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Cardiac disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
External ear inflammation	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Eye disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Blepharitis	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	Any	1 (8)	2 (17)	5 (42)	0 (0)	2 (17)	10 (17)
Abdominal discomfort	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Abdominal pain	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	Mild	1 (8)	0 (0)	2 (17)	0 (0)	2 (17)	5 (8)
Dyspepsia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Gastrointestinal disorder	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_5_1.sas (Page 17 of 46)

Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Haemorrhoids thrombosed	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Nausea	Mild	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Toothache	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
	Moderate	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
General disorders and administration site conditions	Any	5 (42)	2 (17)	12 (100)	10 (83)	11 (92)	40 (67)
Axillary pain	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Chest pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Fatigue	Mild	3 (25)	0 (0)	4 (33)	6 (50)	1 (8)	14 (23)
	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Influenza like illness	Mild	1 (8)	0 (0)	5 (42)	0 (0)	3 (25)	9 (15)
	Moderate	1 (8)	0 (0)	3 (25)	2 (17)	1 (8)	7 (12)
Injection site haematoma	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Injection site pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Injection site reaction	Mild	2 (17)	0 (0)	6 (50)	9 (75)	10 (83)	27 (45)
	Moderate	0 (0)	0 (0)	6 (50)	1 (8)	0 (0)	7 (12)
Malaise	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Non-cardiac chest pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site erythema	Mild	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Vessel puncture site haematoma	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site swelling	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Infections and infestations	Any	1 (8)	1 (8)	3 (25)	0 (0)	1 (8)	6 (10)
Cestode infection	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Gastroenteritis	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Nasopharyngitis	Moderate	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Oral herpes	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Rhinitis	Mild	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Tonsillitis	Moderate	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Injury, poisoning and procedural complications	Any	3 (25)	3 (25)	1 (8)	0 (0)	0 (0)	7 (12)
Animal bite	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Ankle fracture	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Arthropod sting	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Face injury	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin abrasion	Mild	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
Sunburn	Mild	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (3)
	Moderate	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Investigations	Any	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Amylase increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
C-reactive protein increased	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Lipase increased	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	Any	0 (0)	0 (0)	3 (25)	0 (0)	1 (8)	4 (7)
Arthralgia	Mild	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
Back pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Muscle spasms	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Myalgia	Mild	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
Neck pain	Severe	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Tendon pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	Any	1 (8)	1 (8)	4 (33)	3 (25)	2 (17)	11 (18)
Dizziness	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Headache	Mild	0 (0)	1 (8)	3 (25)	1 (8)	1 (8)	6 (10)
	Moderate	0 (0)	0 (0)	1 (8)	2 (17)	0 (0)	3 (5)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Headache	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Hypoaesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Orthostatic intolerance	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Sensory disturbance	Mild	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Renal and urinary disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal colic	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Reproductive system and breast disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Dysmenorrhoea	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	4 (7)
Nasal congestion	Mild	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	Mild	0 (0)	1 (8)	1 (8)	1 (8)	0 (0)	3 (5)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Painful respiration	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin and subcutaneous tissue disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Seborrhoeic dermatitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin irritation	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (3)
Hot flush	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Blood and lymphatic system disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
External ear inflammation	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	Any	0 (0)	1 (8)	0 (0)	1 (3)	8 (8)
Abdominal discomfort	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Diarrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Dyspepsia	Mild	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Nausea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Toothache	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	Any	1 (8)	0 (0)	1 (8)	2 (6)	40 (42)
Chest pain	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Fatigue	Mild	0 (0)	0 (0)	0 (0)	0 (0)	14 (15)
Influenza like illness	Mild	1 (8)	0 (0)	0 (0)	1 (3)	9 (9)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Influenza like illness	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injection site reaction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	28 (29)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
Non-cardiac chest pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site erythema	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site swelling	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastroenteritis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	Any	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
Amylase increased	Mild	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
C-reactive protein increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Lipase increased	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	Any	2 (17)	0 (0)	1 (8)	3 (8)	5 (5)
Arthralgia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Back pain	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Musculoskeletal pain	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Myalgia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tendon pain	Moderate	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Nervous system disorders	Any	2 (17)	0 (0)	1 (8)	3 (8)	11 (11)
Dizziness	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Headache	Mild	1 (8)	0 (0)	0 (0)	1 (3)	6 (6)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Hypoaesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Orthostatic intolerance	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal and urinary disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to Day 7 after prime

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Renal colic	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin irritation	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Blood and lymphatic system disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
External ear inflammation	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Blepharitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	Any	0 (0)	1 (8)	1 (8)	2 (6)	11 (11)
Abdominal discomfort	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
Dyspepsia	Mild	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Nausea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Toothache	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
General disorders and administration site conditions	Any	2 (17)	0 (0)	1 (8)	3 (8)	41 (43)
Chest pain	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Fatigue	Mild	0 (0)	0 (0)	0 (0)	0 (0)	14 (15)
Influenza like illness	Mild	1 (8)	0 (0)	0 (0)	1 (3)	9 (9)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site haematoma	Mild	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Injection site pain	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Injection site reaction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	28 (29)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
Non-cardiac chest pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site erythema	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site swelling	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Infections and infestations	Any	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Cestode infection	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastroenteritis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	Any	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Arthropod sting	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sunburn	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Investigations	Any	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
Amylase increased	Mild	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
C-reactive protein increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lipase increased	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	Any	2 (17)	0 (0)	2 (17)	4 (11)	8 (8)
Arthralgia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Back pain	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Musculoskeletal pain	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Myalgia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Neck pain	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tendon pain	Moderate	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Nervous system disorders	Any	2 (17)	1 (8)	2 (17)	5 (14)	13 (14)
Dizziness	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Headache	Mild	1 (8)	1 (8)	0 (0)	2 (6)	7 (7)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Hypoaesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Orthostatic intolerance	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal and urinary disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Renal colic	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	Any	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Seborrhoeic dermatitis	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Skin irritation	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Boost up to Day 7 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Cardiac disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	Any	1 (8)	0 (0)	0 (0)	1 (3)	11 (11)
Axillary pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	Mild	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Influenza like illness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site reaction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Malaise	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Vessel puncture site pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Oral herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Boost up to Day 7 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Tonsillitis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Animal bite	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	Any	1 (8)	0 (0)	2 (17)	3 (8)	4 (4)
Dizziness	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Headache	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Orthostatic intolerance	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Nasal congestion	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Boost up to Day 7 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Skin and subcutaneous tissue disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin irritation	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Hot flush	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Cardiac disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	Any	0 (0)	2 (17)	0 (0)	2 (6)	3 (3)
Gastrointestinal disorder	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Haemorrhoids thrombosed	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Toothache	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
General disorders and administration site conditions	Any	1 (8)	0 (0)	0 (0)	1 (3)	13 (14)
Axillary pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	Mild	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Injection site reaction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Injection site reaction	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Malaise	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	Any	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Nasopharyngitis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oral herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tonsillitis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	Any	0 (0)	2 (17)	0 (0)	2 (6)	7 (7)
Animal bite	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ankle fracture	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Face injury	Severe	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin abrasion	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Sunburn	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Sunburn	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	Any	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Muscle spasms	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Nervous system disorders	Any	1 (8)	1 (8)	3 (25)	5 (14)	8 (8)
Dizziness	Mild	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Headache	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	1 (8)	2 (17)	3 (8)	4 (4)
Orthostatic intolerance	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Sensory disturbance	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Reproductive system and breast disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysmenorrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	1 (8)	0 (0)	1 (3)	5 (5)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Boost up to Day 28 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Nasal congestion	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Painful respiration	Mild	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin and subcutaneous tissue disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin irritation	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Hot flush	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_5_1.sas (Page 39 of 46)

Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Blood and lymphatic system disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ear and labyrinth disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
External ear inflammation	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Blepharitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	Any	0 (0)	3 (25)	1 (8)	4 (11)	14 (15)
Abdominal discomfort	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
Dyspepsia	Mild	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Gastrointestinal disorder	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Haemorrhoids thrombosed	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nausea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Toothache	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
General disorders and administration site conditions	Any	3 (25)	0 (0)	1 (8)	4 (11)	44 (46)
Axillary pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Chest pain	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Fatigue	Mild	1 (8)	0 (0)	0 (0)	1 (3)	15 (16)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	Mild	1 (8)	0 (0)	0 (0)	1 (3)	10 (10)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
Injection site haematoma	Mild	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Injection site pain	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Injection site reaction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	27 (28)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
Malaise	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Non-cardiac chest pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site erythema	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site swelling	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	Any	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
Cestode infection	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastroenteritis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Oral herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tonsillitis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	Any	0 (0)	2 (17)	0 (0)	2 (6)	9 (9)
Animal bite	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ankle fracture	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Arthropod sting	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Face injury	Severe	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin abrasion	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Sunburn	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	Any	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
Amylase increased	Mild	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
C-reactive protein increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Lipase increased	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	Any	2 (17)	1 (8)	2 (17)	5 (14)	9 (9)
Arthralgia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Back pain	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Muscle spasms	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal pain	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Myalgia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Neck pain	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tendon pain	Moderate	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Nervous system disorders	Any	2 (17)	2 (17)	4 (33)	8 (22)	19 (20)
Dizziness	Mild	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Headache	Mild	1 (8)	1 (8)	0 (0)	2 (6)	8 (8)
	Moderate	0 (0)	1 (8)	2 (17)	3 (8)	6 (6)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Headache	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Hypoaesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Orthostatic intolerance	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Sensory disturbance	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal colic	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Reproductive system and breast disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysmenorrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	1 (8)	0 (0)	1 (3)	5 (5)
Nasal congestion	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Painful respiration	Mild	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin and subcutaneous tissue disorders	Any	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Seborrhoeic dermatitis	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Skin irritation	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
Hot flush	Mild	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to Day 7 after prime

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Blood and lymphatic system disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	Any	1 (9)	1 (8)	3 (27)	0 (0)	2 (17)	7 (12)
Abdominal discomfort	Mild	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Diarrhoea	Mild	1 (9)	0 (0)	1 (9)	0 (0)	2 (17)	4 (7)
Dyspepsia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nausea	Mild	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Toothache	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
General disorders and administration site conditions	Any	3 (27)	1 (8)	11 (100)	10 (83)	11 (92)	36 (62)
Chest pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Fatigue	Mild	3 (27)	0 (0)	4 (36)	6 (50)	1 (8)	14 (24)
Influenza like illness	Mild	0 (0)	0 (0)	3 (27)	0 (0)	3 (25)	6 (10)
	Moderate	0 (0)	0 (0)	0 (0)	2 (17)	1 (8)	3 (5)
Injection site haematoma	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to Day 7 after prime

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Injection site reaction	Mild	1 (9)	0 (0)	6 (55)	9 (75)	10 (83)	26 (45)
	Moderate	0 (0)	0 (0)	5 (45)	1 (8)	0 (0)	6 (10)
Non-cardiac chest pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site erythema	Mild	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Vessel puncture site haematoma	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site swelling	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Infections and infestations	Any	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Gastroenteritis	Mild	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Investigations	Any	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Amylase increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
C-reactive protein increased	Mild	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Lipase increased	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	Any	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to Day 7 after prime

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Arthralgia	Mild	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Back pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Myalgia	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Tendon pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	Any	0 (0)	0 (0)	4 (36)	2 (17)	2 (17)	8 (14)
Dizziness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	Mild	0 (0)	0 (0)	3 (27)	1 (8)	1 (8)	5 (9)
	Moderate	0 (0)	0 (0)	1 (9)	1 (8)	0 (0)	2 (3)
Hypoaesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Orthostatic intolerance	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal colic	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to Day 7 after prime

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Oropharyngeal pain	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin and subcutaneous tissue disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin irritation	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Hot flush	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Blood and lymphatic system disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Eye disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Blepharitis	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	Any	1 (9)	1 (8)	4 (36)	0 (0)	2 (17)	8 (14)
Abdominal discomfort	Mild	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Abdominal pain	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	Mild	1 (9)	0 (0)	1 (9)	0 (0)	2 (17)	4 (7)
Dyspepsia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nausea	Mild	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Toothache	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
General disorders and administration site conditions	Any	3 (27)	1 (8)	11 (100)	10 (83)	11 (92)	36 (62)
Chest pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Fatigue	Mild	3 (27)	0 (0)	4 (36)	6 (50)	1 (8)	14 (24)
Influenza like illness	Mild	0 (0)	0 (0)	3 (27)	0 (0)	3 (25)	6 (10)
	Moderate	0 (0)	0 (0)	0 (0)	2 (17)	1 (8)	3 (5)
Injection site haematoma	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Injection site pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injection site reaction	Mild	1 (9)	0 (0)	6 (55)	9 (75)	10 (83)	26 (45)
	Moderate	0 (0)	0 (0)	5 (45)	1 (8)	0 (0)	6 (10)
Non-cardiac chest pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site erythema	Mild	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Vessel puncture site haematoma	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site swelling	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Infections and infestations	Any	1 (9)	0 (0)	1 (9)	0 (0)	1 (8)	3 (5)
Cestode infection	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Gastroenteritis	Mild	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Rhinitis	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Injury, poisoning and procedural complications	Any	1 (9)	1 (8)	1 (9)	0 (0)	0 (0)	3 (5)
Arthropod sting	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Sunburn	Mild	1 (9)	0 (0)	1 (9)	0 (0)	0 (0)	2 (3)
Investigations	Any	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Amylase increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
C-reactive protein increased	Mild	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Lipase increased	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	Any	0 (0)	0 (0)	3 (27)	0 (0)	1 (8)	4 (7)
Arthralgia	Mild	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Back pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Myalgia	Mild	0 (0)	0 (0)	1 (9)	0 (0)	1 (8)	2 (3)
Neck pain	Severe	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Tendon pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	Any	0 (0)	0 (0)	4 (36)	2 (17)	2 (17)	8 (14)
Dizziness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	Mild	0 (0)	0 (0)	3 (27)	1 (8)	1 (8)	5 (9)
	Moderate	0 (0)	0 (0)	1 (9)	1 (8)	0 (0)	2 (3)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Hypoaesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Orthostatic intolerance	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal colic	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Oropharyngeal pain	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Skin and subcutaneous tissue disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Seborrhoeic dermatitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin irritation	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Hot flush	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Boost up to Day 7 after boost

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Cardiac disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
General disorders and administration site conditions	Any	0 (0)	0 (0)	10 (91)	0 (0)	0 (0)	10 (17)
Axillary pain	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
	Moderate	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Fatigue	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Influenza like illness	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
	Moderate	0 (0)	0 (0)	3 (27)	0 (0)	0 (0)	3 (5)
Injection site reaction	Mild	0 (0)	0 (0)	7 (64)	0 (0)	0 (0)	7 (12)
	Moderate	0 (0)	0 (0)	3 (27)	0 (0)	0 (0)	3 (5)
Malaise	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Vessel puncture site pain	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Infections and infestations	Any	1 (9)	0 (0)	1 (9)	0 (0)	0 (0)	2 (3)
Oral herpes	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Boost up to Day 7 after boost

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Tonsillitis	Moderate	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Injury, poisoning and procedural complications	Any	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Animal bite	Mild	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Nervous system disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Dizziness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Orthostatic intolerance	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	1 (8)	1 (9)	1 (8)	1 (8)	4 (7)
Nasal congestion	Mild	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	Mild	0 (0)	1 (8)	1 (9)	1 (8)	0 (0)	3 (5)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Boost up to Day 7 after boost

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Skin and subcutaneous tissue disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin irritation	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Hot flush	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Boost up to Day 28 after boost

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Cardiac disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Gastrointestinal disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorder	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Haemorrhoids thrombosed	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Toothache	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
General disorders and administration site conditions	Any	1 (9)	1 (8)	10 (91)	0 (0)	0 (0)	12 (21)
Axillary pain	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
	Moderate	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Fatigue	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Influenza like illness	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
	Moderate	1 (9)	0 (0)	3 (27)	0 (0)	0 (0)	4 (7)
Injection site reaction	Mild	0 (0)	0 (0)	7 (64)	0 (0)	0 (0)	7 (12)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Boost up to Day 28 after boost

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Injection site reaction	Moderate	0 (0)	0 (0)	3 (27)	0 (0)	0 (0)	3 (5)
Malaise	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Infections and infestations	Any	1 (9)	1 (8)	1 (9)	0 (0)	0 (0)	3 (5)
Nasopharyngitis	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Oral herpes	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Tonsillitis	Moderate	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Injury, poisoning and procedural complications	Any	2 (18)	2 (17)	1 (9)	0 (0)	0 (0)	5 (9)
Animal bite	Mild	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Ankle fracture	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Face injury	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin abrasion	Mild	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
Sunburn	Mild	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Boost up to Day 28 after boost

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Sunburn	Moderate	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Musculoskeletal and connective tissue disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Muscle spasms	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	Any	1 (9)	1 (8)	0 (0)	1 (8)	0 (0)	3 (5)
Dizziness	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Headache	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
	Moderate	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Orthostatic intolerance	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Sensory disturbance	Mild	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Reproductive system and breast disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Dysmenorrhoea	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	1 (8)	1 (9)	1 (8)	1 (8)	4 (7)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Boost up to Day 28 after boost

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Nasal congestion	Mild	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	Mild	0 (0)	1 (8)	1 (9)	1 (8)	0 (0)	3 (5)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Painful respiration	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin and subcutaneous tissue disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Skin irritation	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Hot flush	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Blood and lymphatic system disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Lymphadenopathy	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Cardiac disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Palpitations	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Eye disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Blepharitis	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Gastrointestinal disorders	Any	1 (9)	2 (17)	4 (36)	0 (0)	2 (17)	9 (16)
Abdominal discomfort	Mild	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Abdominal pain	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	Mild	1 (9)	0 (0)	1 (9)	0 (0)	2 (17)	4 (7)
Dyspepsia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Gastrointestinal disorder	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Haemorrhoids thrombosed	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Nausea	Mild	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Toothache	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
	Moderate	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
General disorders and administration site conditions	Any	4 (36)	2 (17)	11 (100)	10 (83)	11 (92)	38 (66)
Axillary pain	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
	Moderate	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Chest pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Fatigue	Mild	3 (27)	0 (0)	4 (36)	6 (50)	1 (8)	14 (24)
	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Influenza like illness	Mild	0 (0)	0 (0)	4 (36)	0 (0)	3 (25)	7 (12)
	Moderate	1 (9)	0 (0)	3 (27)	2 (17)	1 (8)	7 (12)
Injection site haematoma	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Injection site pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Injection site reaction	Mild	1 (9)	0 (0)	5 (45)	9 (75)	10 (83)	25 (43)
	Moderate	0 (0)	0 (0)	6 (55)	1 (8)	0 (0)	7 (12)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Malaise	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Non-cardiac chest pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site erythema	Mild	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Vessel puncture site haematoma	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Vessel puncture site pain	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Vessel puncture site swelling	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Infections and infestations	Any	1 (9)	1 (8)	2 (18)	0 (0)	1 (8)	5 (9)
Cestode infection	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Gastroenteritis	Mild	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Nasopharyngitis	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Oral herpes	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Rhinitis	Mild	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Tonsillitis	Moderate	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Injury, poisoning and procedural complications	Any	3 (27)	3 (25)	1 (9)	0 (0)	0 (0)	7 (12)
Animal bite	Mild	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Ankle fracture	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Arthropod sting	Moderate	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Face injury	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin abrasion	Mild	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
Sunburn	Mild	2 (18)	0 (0)	0 (0)	0 (0)	0 (0)	2 (3)
	Moderate	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Investigations	Any	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Amylase increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
C-reactive protein increased	Mild	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Lipase increased	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	Any	0 (0)	0 (0)	3 (27)	0 (0)	1 (8)	4 (7)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Arthralgia	Mild	0 (0)	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Back pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Muscle spasms	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Myalgia	Mild	0 (0)	0 (0)	1 (9)	0 (0)	1 (8)	2 (3)
Neck pain	Severe	0 (0)	0 (0)	1 (9)	0 (0)	0 (0)	1 (2)
Tendon pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Nervous system disorders	Any	1 (9)	1 (8)	4 (36)	3 (25)	2 (17)	11 (19)
Dizziness	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Headache	Mild	0 (0)	1 (8)	3 (27)	1 (8)	1 (8)	6 (10)
	Moderate	0 (0)	0 (0)	1 (9)	2 (17)	0 (0)	3 (5)
	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Hypoaesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Orthostatic intolerance	Severe	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Sensory disturbance	Mild	1 (9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Insomnia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Renal and urinary disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Renal colic	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Reproductive system and breast disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Dysmenorrhoea	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	1 (8)	1 (9)	1 (8)	1 (8)	4 (7)
Nasal congestion	Mild	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Oropharyngeal pain	Mild	0 (0)	1 (8)	1 (9)	1 (8)	0 (0)	3 (5)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
Painful respiration	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin and subcutaneous tissue disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Younger dose ranging cohorts					
System organ class Preferred term	Severity/ Toxicity grade [1]	1 µg (N=11) n (%)	3 µg (N=12) n (%)	10 µg (N=11) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=58) n (%)
Seborrhoeic dermatitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Skin irritation	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Vascular disorders	Any	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (3)
Hot flush	Mild	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to Day 7 after prime

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Blood and lymphatic system disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	Any	0 (0)	1 (8)	0 (0)	1 (3)	8 (9)
Abdominal discomfort	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Diarrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Dyspepsia	Mild	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Nausea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Toothache	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	Any	1 (8)	0 (0)	1 (8)	2 (6)	38 (40)
Chest pain	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Fatigue	Mild	0 (0)	0 (0)	0 (0)	0 (0)	14 (15)
Influenza like illness	Mild	1 (8)	0 (0)	0 (0)	1 (3)	7 (7)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to Day 7 after prime

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Injection site reaction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	26 (28)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
Non-cardiac chest pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site erythema	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site swelling	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastroenteritis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	Any	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
Amylase increased	Mild	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
C-reactive protein increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lipase increased	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	Any	2 (17)	0 (0)	1 (8)	3 (8)	5 (5)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to Day 7 after prime

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Arthralgia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Back pain	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Musculoskeletal pain	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Myalgia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tendon pain	Moderate	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Nervous system disorders	Any	2 (17)	0 (0)	1 (8)	3 (8)	11 (12)
Dizziness	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Headache	Mild	1 (8)	0 (0)	0 (0)	1 (3)	6 (6)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Hypoaesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Orthostatic intolerance	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal and urinary disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal colic	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to Day 7 after prime

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Oropharyngeal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin and subcutaneous tissue disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin irritation	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Blood and lymphatic system disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Blepharitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	Any	0 (0)	1 (8)	1 (8)	2 (6)	10 (11)
Abdominal discomfort	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Dyspepsia	Mild	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Nausea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Toothache	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	Any	2 (17)	0 (0)	1 (8)	3 (8)	39 (41)
Chest pain	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Fatigue	Mild	0 (0)	0 (0)	0 (0)	0 (0)	14 (15)
Influenza like illness	Mild	1 (8)	0 (0)	0 (0)	1 (3)	7 (7)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site haematoma	Mild	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Injection site pain	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Injection site reaction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	26 (28)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
Non-cardiac chest pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site erythema	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site swelling	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	Any	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Cestode infection	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Gastroenteritis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	Any	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Arthropod sting	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Sunburn	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Investigations	Any	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
Amylase increased	Mild	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
C-reactive protein increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lipase increased	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	Any	2 (17)	0 (0)	2 (17)	4 (11)	8 (9)
Arthralgia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Back pain	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Musculoskeletal pain	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Myalgia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Neck pain	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tendon pain	Moderate	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Nervous system disorders	Any	2 (17)	1 (8)	2 (17)	5 (14)	13 (14)
Dizziness	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Headache	Mild	1 (8)	1 (8)	0 (0)	2 (6)	7 (7)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Hypoaesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Orthostatic intolerance	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal and urinary disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal colic	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to boost or Day 28 after prime (whatever comes first)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Skin and subcutaneous tissue disorders	Any	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Seborrhoeic dermatitis	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Skin irritation	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hot flush	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Boost up to Day 7 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Cardiac disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
General disorders and administration site conditions	Any	1 (8)	0 (0)	0 (0)	1 (3)	11 (12)
Axillary pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	Mild	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Influenza like illness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Injection site reaction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Malaise	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Vessel puncture site pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	Any	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Oral herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Boost up to Day 7 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Tonsillitis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Animal bite	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nervous system disorders	Any	1 (8)	0 (0)	2 (17)	3 (8)	4 (4)
Dizziness	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Headache	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Orthostatic intolerance	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Nasal congestion	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Boost up to Day 7 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Skin and subcutaneous tissue disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin irritation	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Hot flush	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Boost up to Day 28 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Cardiac disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	Any	0 (0)	2 (17)	0 (0)	2 (6)	3 (3)
Gastrointestinal disorder	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Haemorrhoids thrombosed	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Toothache	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
General disorders and administration site conditions	Any	1 (8)	0 (0)	0 (0)	1 (3)	13 (14)
Axillary pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Fatigue	Mild	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Injection site reaction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Boost up to Day 28 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Injection site reaction	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Malaise	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	Any	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
Nasopharyngitis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oral herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tonsillitis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	Any	0 (0)	2 (17)	0 (0)	2 (6)	7 (7)
Animal bite	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ankle fracture	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Face injury	Severe	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin abrasion	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Sunburn	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Boost up to Day 28 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Sunburn	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Musculoskeletal and connective tissue disorders	Any	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Muscle spasms	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Nervous system disorders	Any	1 (8)	1 (8)	3 (25)	5 (14)	8 (9)
Dizziness	Mild	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Headache	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	1 (8)	2 (17)	3 (8)	4 (4)
Orthostatic intolerance	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Sensory disturbance	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Reproductive system and breast disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysmenorrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	1 (8)	0 (0)	1 (3)	5 (5)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Boost up to Day 28 after boost

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Nasal congestion	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Painful respiration	Mild	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin and subcutaneous tissue disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Skin irritation	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Hot flush	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Blood and lymphatic system disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lymphadenopathy	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cardiac disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Palpitations	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Eye disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Blepharitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastrointestinal disorders	Any	0 (0)	3 (25)	1 (8)	4 (11)	13 (14)
Abdominal discomfort	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Abdominal pain	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Diarrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Dyspepsia	Mild	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Gastrointestinal disorder	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Haemorrhoids thrombosed	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nausea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Toothache	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
General disorders and administration site conditions	Any	3 (25)	0 (0)	1 (8)	4 (11)	42 (45)
Axillary pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Chest pain	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Fatigue	Mild	1 (8)	0 (0)	0 (0)	1 (3)	15 (16)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza like illness	Mild	1 (8)	0 (0)	0 (0)	1 (3)	8 (9)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
Injection site haematoma	Mild	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Injection site pain	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Injection site reaction	Mild	0 (0)	0 (0)	0 (0)	0 (0)	25 (27)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Malaise	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Non-cardiac chest pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site erythema	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site haematoma	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vessel puncture site swelling	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Infections and infestations	Any	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
Cestode infection	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Gastroenteritis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Nasopharyngitis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oral herpes	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Rhinitis	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Tonsillitis	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Injury, poisoning and procedural complications	Any	0 (0)	2 (17)	0 (0)	2 (6)	9 (10)
Animal bite	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Ankle fracture	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Arthropod sting	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Face injury	Severe	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin abrasion	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Sunburn	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Investigations	Any	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
Amylase increased	Mild	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
C-reactive protein increased	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Lipase increased	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal and connective tissue disorders	Any	2 (17)	1 (8)	2 (17)	5 (14)	9 (10)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Arthralgia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Back pain	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Muscle spasms	Moderate	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Musculoskeletal pain	Mild	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Myalgia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Neck pain	Severe	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tendon pain	Moderate	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Nervous system disorders	Any	2 (17)	2 (17)	4 (33)	8 (22)	19 (20)
Dizziness	Mild	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Headache	Mild	1 (8)	1 (8)	0 (0)	2 (6)	8 (9)
	Moderate	0 (0)	1 (8)	2 (17)	3 (8)	6 (6)
	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Hypoaesthesia	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Orthostatic intolerance	Severe	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Sensory disturbance	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Psychiatric disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Insomnia	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Renal and urinary disorders	Any	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Renal colic	Moderate	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
Reproductive system and breast disorders	Any	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Dysmenorrhoea	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Respiratory, thoracic and mediastinal disorders	Any	0 (0)	1 (8)	0 (0)	1 (3)	5 (5)
Nasal congestion	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Oropharyngeal pain	Mild	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Painful respiration	Mild	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
Skin and subcutaneous tissue disorders	Any	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

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Table 14.3.1-3.5.1-3: Frequency of subjects with TEAEs by worst grade and SOC and PT - BNT162b2

Safety boost set

Prime up to Day 28 after boost or after prime (if no boost)

		Older dose ranging cohorts				
System organ class Preferred term	Severity/ Toxicity grade [1]	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=94) n (%)
Seborrhoeic dermatitis	Mild	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
Skin irritation	Mild	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Vascular disorders	Any	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
Hot flush	Mild	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
	Moderate	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N. Adverse events are coded using MedDRA version MedDRA 23.0.
[1] Depending on the effective version of the protocol, either severity or toxicity grade of a TEAE was assessed.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic; N/A = not available; PT = preferred term; SOC = system organ class; TEAE = treatment emergent adverse events.

Program: Tsaf_AE_5_1.sas (Page 46 of 46)

Listing 14.3.1-3.7.1-3: Listing of serious adverse events - BNT162b2

Safety set

Subject number/ Dose group	Reported term/ Coded term	Start date/ time	End date/ time	Duration [h]/ Days since last dose	Action taken/ Concomitant or additional treatment given	Relationship/ Outcome	Grade/ Seriousness	TEAE/ TEAESI	Epi-/pandemic related indicator/ Dose limiting toxicity
20215 20 µg Older	fracture leg ankle Ankle fracture	14OCT2020 14:20		- 23	Not Applicable Yes	Not Related Recovering/Resolving	Moderate Yes	Yes No	No No

Adverse events are coded using MedDRA version MedDRA 23.0.
TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.

Program: Tsaf_AE_71.sas (Page 1 of 1)

14.3.2 Further safety endpoints
14.3.2-1 Compliance

Table 14.3.2-1.1-3: IMP compliance - BNT162b2

Safety set

	Younger dose ranging cohorts					
	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Subjects receiving first immunization	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
Subjects receiving boost immunization	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_IMP_1_1.sas (Page 1 of 2)

Table 14.3.2-1.1-3: IMP compliance - BNT162b2

Safety set

	Older dose ranging cohorts				
	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Subjects receiving first immunization	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
Subjects receiving boost immunization	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_IMP_1_1.sas (Page 2 of 2)

Table 14.3.2-1.2-3: Diary compliance local reactions - BNT162b2

Safety set

		Younger dose ranging cohorts					
	Day after immunization	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
After prime	0	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	1	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	2	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	3	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	4	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	5	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	6	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	7	12 (100)	11 (92)	2 (17)	9 (75)	11 (92)	45 (75)
After boost	0	11 (92)	12 (100)	11 (92)	11 (92)	12 (100)	57 (95)
	1	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
	2	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
	3	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
	4	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
	5	10 (83)	12 (100)	11 (92)	12 (100)	12 (100)	57 (95)
	6	10 (83)	12 (100)	11 (92)	12 (100)	12 (100)	57 (95)
	7	10 (83)	11 (92)	11 (92)	12 (100)	10 (83)	54 (90)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with diary compliance on local reactions on the specified day.

Program: Tfsaf_diary_1_2.sas (Page 1 of 2)

Table 14.3.2-1.2-3: Diary compliance local reactions - BNT162b2

Safety set

		Older dose ranging cohorts				
	Day after immunization	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
After prime	0	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	1	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	2	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	3	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	4	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	5	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	6	12 (100)	12 (100)	11 (92)	35 (97)	95 (99)
	7	0 (0)	6 (50)	0 (0)	6 (17)	51 (53)
After boost	0	12 (100)	12 (100)	12 (100)	36 (100)	93 (97)
	1	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
	2	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
	3	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
	4	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
	5	12 (100)	12 (100)	11 (92)	35 (97)	92 (96)
	6	12 (100)	12 (100)	7 (58)	31 (86)	88 (92)
	7	0 (0)	12 (100)	3 (25)	15 (42)	69 (72)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with diary compliance on local reactions on the specified day.

Program: Tfsaf_diary_1_2.sas (Page 2 of 2)

Table 14.3.2-1.3-3: Diary compliance systemic reactions - BNT162b2

Safety set

		Younger dose ranging cohorts					
	Day after immunization	1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
After prime	0	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	1	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	2	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	3	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	4	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	5	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	6	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	7	12 (100)	11 (92)	2 (17)	9 (75)	11 (92)	45 (75)
After boost	0	11 (92)	12 (100)	11 (92)	11 (92)	12 (100)	57 (95)
	1	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
	2	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
	3	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
	4	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
	5	10 (83)	12 (100)	11 (92)	12 (100)	12 (100)	57 (95)
	6	10 (83)	12 (100)	11 (92)	12 (100)	12 (100)	57 (95)
	7	10 (83)	11 (92)	11 (92)	12 (100)	10 (83)	54 (90)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with diary compliance on systemic reactions on the specified day.

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Table 14.3.2-1.3-3: Diary compliance systemic reactions - BNT162b2

Safety set

		Older dose ranging cohorts				
	Day after immunization	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
After prime	0	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	1	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	2	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	3	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	4	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	5	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	6	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	7	0 (0)	6 (50)	0 (0)	6 (17)	51 (53)
After boost	0	12 (100)	12 (100)	12 (100)	36 (100)	93 (97)
	1	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
	2	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
	3	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
	4	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
	5	12 (100)	12 (100)	12 (100)	36 (100)	93 (97)
	6	12 (100)	12 (100)	7 (58)	31 (86)	88 (92)
	7	0 (0)	12 (100)	3 (25)	15 (42)	69 (72)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with diary compliance on systemic reactions on the specified day.

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14.3.2-2 Laboratory
14.3.2-2.1 Descriptive statistics

Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Basophils (Blood) [10^9/L]	Day -30 to 0	n	12	9	12	12	12	57
		Mean (SD)	0.040 (0.025)	0.050 (0.009)	0.042 (0.017)	0.039 (0.019)	0.040 (0.024)	0.042 (0.020)
		Min	0.01	0.04	0.02	0.01	0.01	0.01
		Median	0.035	0.050	0.040	0.040	0.035	0.040
		Max	0.10	0.06	0.08	0.07	0.09	0.10
	Day 1	n	11	12	12	12	11	58
		Mean (SD)	0.036 (0.019)	0.043 (0.017)	0.040 (0.014)	0.044 (0.022)	0.044 (0.022)	0.041 (0.018)
		Min	0.01	0.02	0.02	0.01	0.02	0.01
		Median	0.030	0.040	0.040	0.050	0.040	0.040
		Max	0.06	0.08	0.06	0.08	0.08	0.08
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	0.044 (0.032)	0.043 (0.015)	0.038 (0.011)	0.036 (0.011)	0.039 (0.023)	0.040 (0.020)
		Min	0.00	0.02	0.02	0.02	0.01	0.00
		Median	0.040	0.040	0.040	0.035	0.040	0.040
		Max	0.12	0.07	0.05	0.05	0.09	0.12

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Basophils (Blood) [10^9/L]	Day 8	n	12	12	11	12	11	58
		Mean (SD)	0.043 (0.023)	0.043 (0.015)	0.038 (0.012)	0.035 (0.014)	0.040 (0.019)	0.040 (0.017)
		Min	0.00	0.02	0.02	0.01	0.02	0.00
		Median	0.040	0.045	0.040	0.035	0.040	0.040
		Max	0.09	0.07	0.06	0.06	0.08	0.09
	Day 29	n	11	11	11	11	10	54
		Mean (SD)	0.035 (0.016)	0.041 (0.016)	0.039 (0.014)	0.037 (0.017)	0.042 (0.022)	0.039 (0.017)
		Min	0.01	0.02	0.02	0.02	0.02	0.01
		Median	0.040	0.040	0.040	0.030	0.035	0.040
		Max	0.06	0.07	0.06	0.07	0.08	0.08
	Day 50	n	9	12	12	12	12	57
		Mean (SD)	0.031 (0.013)	0.042 (0.011)	0.044 (0.018)	0.034 (0.011)	0.042 (0.024)	0.039 (0.017)
		Min	0.01	0.03	0.02	0.01	0.01	0.01
		Median	0.030	0.040	0.040	0.030	0.040	0.040
		Max	0.05	0.06	0.08	0.05	0.10	0.10

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Basophils (Blood Smear) [10^9/L]	Day -30 to 0	n	0	3	0	0	0	3
		Mean (SD)	- (-)	0.020 (0.035)	- (-)	- (-)	- (-)	0.020 (0.035)
		Min	-	0.00	-	-	-	0.00
		Median	-	0.000	-	-	-	0.000
		Max	-	0.06	-	-	-	0.06
	Day 1	n	1	0	0	0	1	2
		Mean (SD)	0.100 (-)	- (-)	- (-)	- (-)	0.000 (-)	0.050 (-)
		Min	0.10	-	-	-	0.00	0.00
		Median	0.100	-	-	-	0.000	0.050
		Max	0.10	-	-	-	0.00	0.10
	Day 8	n	0	0	1	0	1	2
		Mean (SD)	- (-)	- (-)	0.000 (-)	- (-)	0.000 (-)	0.000 (-)
		Min	-	-	0.00	-	0.00	0.00
		Median	-	-	0.000	-	0.000	0.000
		Max	-	-	0.00	-	0.00	0.00

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Basophils (Blood Smear) [10^9/L]	Day 29	n	1	0	0	1	1	3
		Mean (SD)	0.050 (-)	- (-)	- (-)	0.200 (-)	0.000 (-)	0.083 (0.104)
		Min	0.05	-	-	0.20	0.00	0.00
		Median	0.050	-	-	0.200	0.000	0.050
		Max	0.05	-	-	0.20	0.00	0.20
	Day 50	n	2	0	0	0	0	2
		Mean (SD)	0.185 (-)	- (-)	- (-)	- (-)	- (-)	0.185 (-)
		Min	0.16	-	-	-	-	0.16
		Median	0.185	-	-	-	-	0.185
		Max	0.21	-	-	-	-	0.21
Basophils/Leukocytes (Blood) [%]	Day -30 to 0	n	12	9	12	12	12	57
		Mean (SD)	0.81 (0.47)	0.86 (0.18)	0.75 (0.28)	0.75 (0.37)	0.78 (0.45)	0.78 (0.36)
		Min	0.2	0.6	0.4	0.2	0.2	0.2
		Median	0.70	0.80	0.70	0.75	0.75	0.80
		Max	1.9	1.2	1.4	1.4	1.5	1.9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Basophils/Leukocytes (Blood) [%]	Day 1	n	11	12	12	12	11	58
		Mean (SD)	0.75 (0.45)	0.78 (0.33)	0.79 (0.32)	0.87 (0.41)	0.94 (0.45)	0.83 (0.39)
		Min	0.2	0.4	0.3	0.2	0.4	0.2
		Median	0.60	0.70	0.85	0.95	0.80	0.80
		Max	1.6	1.4	1.2	1.6	1.6	1.6
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	0.88 (0.64)	0.72 (0.32)	0.66 (0.20)	0.66 (0.20)	0.62 (0.29)	0.71 (0.37)
		Min	0.0	0.4	0.3	0.4	0.2	0.0
		Median	0.65	0.65	0.70	0.70	0.70	0.70
		Max	2.1	1.5	0.9	1.0	1.0	2.1
	Day 8	n	12	12	11	12	11	58
		Mean (SD)	0.93 (0.54)	0.77 (0.33)	0.77 (0.27)	0.79 (0.34)	0.84 (0.33)	0.82 (0.37)
		Min	0.0	0.4	0.4	0.2	0.4	0.0
		Median	0.80	0.70	0.80	0.75	0.80	0.80
		Max	1.9	1.4	1.2	1.4	1.4	1.9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Basophils/Leukocytes (Blood) [%]	Day 29	n	11	11	11	11	10	54
		Mean (SD)	0.74 (0.46)	0.81 (0.28)	0.73 (0.28)	0.80 (0.29)	0.91 (0.48)	0.79 (0.36)
		Min	0.2	0.4	0.2	0.5	0.4	0.2
		Median	0.50	0.80	0.80	0.70	0.75	0.75
		Max	1.8	1.3	1.2	1.4	1.9	1.9
	Day 50	n	9	12	12	12	12	57
		Mean (SD)	0.74 (0.40)	0.78 (0.23)	0.85 (0.30)	0.79 (0.34)	0.79 (0.36)	0.79 (0.32)
		Min	0.2	0.5	0.4	0.2	0.2	0.2
		Median	0.60	0.75	0.75	0.80	0.85	0.80
		Max	1.5	1.3	1.3	1.4	1.5	1.5
Basophils/Leukocytes (Blood Smear) [%]	Day -30 to 0	n	0	3	0	0	0	3
		Mean (SD)	- (-)	0.3 (0.6)	- (-)	- (-)	- (-)	0.3 (0.6)
		Min	-	0	-	-	-	0
		Median	-	0.0	-	-	-	0.0
		Max	-	1	-	-	-	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Basophils/Leukocytes (Blood Smear) [%]	Day 1	n	1	0	0	0	1	2
		Mean (SD)	2.0 (-)	- (-)	- (-)	- (-)	0.0 (-)	1.0 (-)
		Min	2	-	-	-	0	0
		Median	2.0	-	-	-	0.0	1.0
		Max	2	-	-	-	0	2
	Day 8	n	0	0	1	0	1	2
		Mean (SD)	- (-)	- (-)	0.0 (-)	- (-)	0.0 (-)	0.0 (-)
		Min	-	-	0	-	0	0
		Median	-	-	0.0	-	0.0	0.0
		Max	-	-	0	-	0	0
	Day 29	n	1	0	0	1	1	3
		Mean (SD)	1.0 (-)	- (-)	- (-)	3.0 (-)	0.0 (-)	1.3 (1.5)
		Min	1	-	-	3	0	0
		Median	1.0	-	-	3.0	0.0	1.0
		Max	1	-	-	3	0	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Basophils/Leukocytes (Blood Smear) [%]	Day 50	n	2	0	0	0	0	2
		Mean (SD)	3.5 (-)	- (-)	- (-)	- (-)	- (-)	3.5 (-)
		Min	3	-	-	-	-	3
		Median	3.5	-	-	-	-	3.5
		Max	4	-	-	-	-	4
Eosinophils (Blood) [10^9/L]	Day -30 to 0	n	12	9	12	12	12	57
		Mean (SD)	0.179 (0.104)	0.141 (0.082)	0.147 (0.068)	0.118 (0.059)	0.127 (0.106)	0.142 (0.086)
		Min	0.06	0.03	0.04	0.03	0.03	0.03
		Median	0.155	0.120	0.150	0.105	0.095	0.120
		Max	0.33	0.31	0.24	0.25	0.41	0.41
	Day 1	n	11	12	12	12	11	58
		Mean (SD)	0.170 (0.092)	0.163 (0.078)	0.123 (0.081)	0.113 (0.046)	0.138 (0.139)	0.141 (0.091)
		Min	0.06	0.04	0.02	0.05	0.02	0.02
		Median	0.180	0.160	0.095	0.100	0.090	0.110
		Max	0.35	0.28	0.25	0.20	0.47	0.47

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Eosinophils (Blood) [10^9/L]	Day 2	n	12	12	12	12	12	60
		Mean (SD)	0.192 (0.112)	0.182 (0.091)	0.131 (0.067)	0.113 (0.047)	0.122 (0.099)	0.148 (0.090)
		Min	0.06	0.04	0.03	0.05	0.02	0.02
		Median	0.195	0.180	0.130	0.110	0.090	0.130
		Max	0.35	0.38	0.25	0.19	0.37	0.38
	Day 8	n	12	12	11	12	11	58
		Mean (SD)	0.197 (0.119)	0.192 (0.109)	0.152 (0.085)	0.144 (0.086)	0.149 (0.121)	0.167 (0.104)
		Min	0.07	0.04	0.04	0.06	0.04	0.04
		Median	0.160	0.175	0.140	0.125	0.130	0.140
		Max	0.42	0.36	0.29	0.32	0.43	0.43
	Day 29	n	11	11	11	11	10	54
		Mean (SD)	0.215 (0.141)	0.135 (0.063)	0.164 (0.097)	0.150 (0.075)	0.140 (0.118)	0.161 (0.103)
		Min	0.05	0.04	0.05	0.06	0.04	0.04
		Median	0.180	0.130	0.150	0.120	0.100	0.130
		Max	0.41	0.23	0.34	0.26	0.44	0.44

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Eosinophils (Blood) [10^9/L]	Day 50	n	9	12	12	12	12	57
		Mean (SD)	0.184 (0.099)	0.146 (0.073)	0.198 (0.134)	0.127 (0.066)	0.152 (0.131)	0.160 (0.104)
		Min	0.05	0.03	0.05	0.04	0.02	0.02
		Median	0.210	0.160	0.155	0.115	0.125	0.140
		Max	0.31	0.30	0.47	0.23	0.44	0.47
Eosinophils (Blood Smear) [10^9/L]	Day -30 to 0	n	0	3	0	0	0	3
		Mean (SD)	- (-)	0.193 (0.135)	- (-)	- (-)	- (-)	0.193 (0.135)
		Min	-	0.06	-	-	-	0.06
		Median	-	0.190	-	-	-	0.190
		Max	-	0.33	-	-	-	0.33
	Day 1	n	1	0	0	0	1	2
		Mean (SD)	0.100 (-)	- (-)	- (-)	- (-)	0.050 (-)	0.075 (-)
		Min	0.10	-	-	-	0.05	0.05
		Median	0.100	-	-	-	0.050	0.075
		Max	0.10	-	-	-	0.05	0.10

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Eosinophils (Blood Smear) [10^9/L]	Day 8	n	0	0	1	0	1	2
		Mean (SD)	- (-)	- (-)	0.230 (-)	- (-)	0.050 (-)	0.140 (-)
		Min	-	-	0.23	-	0.05	0.05
		Median	-	-	0.230	-	0.050	0.140
		Max	-	-	0.23	-	0.05	0.23
	Day 29	n	1	0	0	1	1	3
		Mean (SD)	0.050 (-)	- (-)	- (-)	0.000 (-)	0.070 (-)	0.040 (0.036)
		Min	0.05	-	-	0.00	0.07	0.00
		Median	0.050	-	-	0.000	0.070	0.050
		Max	0.05	-	-	0.00	0.07	0.07
	Day 50	n	2	0	0	0	0	2
		Mean (SD)	0.080 (-)	- (-)	- (-)	- (-)	- (-)	0.080 (-)
		Min	0.05	-	-	-	-	0.05
		Median	0.080	-	-	-	-	0.080
		Max	0.11	-	-	-	-	0.11

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Eosinophils/Leukocytes (Blood) [%]	Day -30 to 0	n	12	9	12	12	12	57
		Mean (SD)	3.48 (1.89)	2.49 (1.47)	2.63 (1.06)	2.35 (1.19)	2.48 (2.25)	2.70 (1.64)
		Min	1.1	0.5	0.6	0.4	0.6	0.4
		Median	3.15	2.10	2.75	2.40	1.90	2.40
		Max	7.4	4.8	4.1	4.3	9.0	9.0
	Day 1	n	11	12	12	12	11	58
		Mean (SD)	3.33 (1.68)	2.95 (1.43)	2.48 (1.64)	2.43 (1.39)	2.75 (2.52)	2.78 (1.73)
		Min	1.0	0.7	0.3	1.0	0.6	0.3
		Median	3.80	2.95	1.90	2.05	2.10	2.20
		Max	6.6	4.8	5.7	5.1	8.9	8.9
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	3.68 (2.06)	3.04 (1.38)	2.33 (1.16)	2.19 (1.29)	1.97 (1.78)	2.64 (1.65)
		Min	1.1	0.8	0.5	0.8	0.4	0.4
		Median	3.45	3.00	2.30	1.85	1.55	2.25
		Max	7.6	5.2	4.7	4.7	7.2	7.6

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Eosinophils/Leukocytes (Blood) [%]	Day 8	n	12	12	11	12	11	58
		Mean (SD)	3.98 (2.36)	3.28 (1.88)	3.11 (1.84)	3.31 (2.06)	3.03 (2.42)	3.35 (2.08)
		Min	1.4	0.8	0.6	1.2	0.8	0.6
		Median	3.05	3.15	2.80	2.60	2.80	2.90
		Max	7.4	6.9	7.5	7.3	9.6	9.6
	Day 29	n	11	11	11	11	10	54
		Mean (SD)	4.15 (2.47)	2.83 (1.68)	3.10 (1.90)	3.27 (1.58)	3.00 (2.46)	3.27 (2.02)
		Min	1.1	0.9	0.8	1.6	1.2	0.8
		Median	3.40	2.60	3.10	2.40	2.20	2.85
		Max	9.2	6.2	6.8	6.0	9.2	9.2
	Day 50	n	9	12	12	12	12	57
		Mean (SD)	4.28 (2.47)	2.75 (1.54)	3.58 (1.97)	2.98 (1.93)	2.82 (2.24)	3.23 (2.03)
		Min	1.0	0.7	1.2	0.8	0.4	0.4
		Median	4.00	2.50	3.15	2.20	2.60	2.90
		Max	8.5	5.4	7.0	6.1	9.0	9.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Eosinophils/Leukocytes (Blood Smear) [%]	Day -30 to 0	n	0	3	0	0	0	3
		Mean (SD)	- (-)	3.3 (2.5)	- (-)	- (-)	- (-)	3.3 (2.5)
		Min	-	1	-	-	-	1
		Median	-	3.0	-	-	-	3.0
		Max	-	6	-	-	-	6
	Day 1	n	1	0	0	0	1	2
		Mean (SD)	2.0 (-)	- (-)	- (-)	- (-)	1.0 (-)	1.5 (-)
		Min	2	-	-	-	1	1
		Median	2.0	-	-	-	1.0	1.5
		Max	2	-	-	-	1	2
	Day 8	n	0	0	1	0	1	2
		Mean (SD)	- (-)	- (-)	4.0 (-)	- (-)	1.0 (-)	2.5 (-)
		Min	-	-	4	-	1	1
		Median	-	-	4.0	-	1.0	2.5
		Max	-	-	4	-	1	4

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Eosinophils/Leukocytes (Blood Smear) [%]	Day 29	n	1	0	0	1	1	3
		Mean (SD)	1.0 (-)	- (-)	- (-)	0.0 (-)	1.0 (-)	0.7 (0.6)
		Min	1	-	-	0	1	0
		Median	1.0	-	-	0.0	1.0	1.0
		Max	1	-	-	0	1	1
	Day 50	n	2	0	0	0	0	2
		Mean (SD)	1.5 (-)	- (-)	- (-)	- (-)	- (-)	1.5 (-)
		Min	1	-	-	-	-	1
		Median	1.5	-	-	-	-	1.5
		Max	2	-	-	-	-	2
Erythrocytes (Blood) [10^{12}/L]	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	4.71 (0.43)	4.63 (0.26)	4.66 (0.41)	4.60 (0.41)	4.82 (0.35)	4.68 (0.37)
		Min	4.0	4.3	4.0	4.0	4.1	4.0
		Median	4.65	4.65	4.55	4.60	4.95	4.60
		Max	5.5	5.1	5.2	5.6	5.2	5.6

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Erythrocytes (Blood) [10^{12}/L]	Day 1	n	12	12	12	12	12	60
		Mean (SD)	4.50 (0.43)	4.37 (0.24)	4.47 (0.46)	4.32 (0.35)	4.63 (0.40)	4.46 (0.39)
		Min	3.9	4.0	3.7	3.8	3.9	3.7
		Median	4.50	4.40	4.60	4.30	4.70	4.45
		Max	5.2	4.7	5.0	5.1	5.2	5.2
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	4.56 (0.41)	4.39 (0.21)	4.47 (0.45)	4.34 (0.38)	4.69 (0.45)	4.49 (0.40)
		Min	4.1	4.1	3.7	3.6	3.9	3.6
		Median	4.55	4.40	4.55	4.30	4.75	4.50
		Max	5.3	4.8	5.0	5.1	5.3	5.3
	Day 8	n	12	12	12	12	12	60
		Mean (SD)	4.48 (0.44)	4.34 (0.27)	4.42 (0.44)	4.31 (0.41)	4.56 (0.41)	4.42 (0.40)
		Min	3.9	4.0	3.5	3.6	3.8	3.5
		Median	4.40	4.35	4.50	4.25	4.65	4.40
		Max	5.2	4.9	4.9	5.2	5.0	5.2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Erythrocytes (Blood) [10^{12}/L]	Day 29	n	12	12	11	12	11	58
		Mean (SD)	4.58 (0.34)	4.38 (0.23)	4.53 (0.42)	4.31 (0.46)	4.51 (0.37)	4.46 (0.37)
		Min	4.1	3.9	3.5	3.4	3.9	3.4
		Median	4.60	4.40	4.50	4.25	4.60	4.50
		Max	5.1	4.7	5.0	5.1	5.0	5.1
	Day 50	n	11	12	12	12	12	59
		Mean (SD)	4.49 (0.30)	4.30 (0.24)	4.46 (0.45)	4.22 (0.26)	4.47 (0.40)	4.38 (0.35)
		Min	4.0	3.8	3.7	3.9	3.7	3.7
		Median	4.50	4.30	4.55	4.10	4.50	4.40
		Max	5.0	4.7	5.0	4.8	5.2	5.2
Hematocrit [L/L]	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	0.450 (0.029)	0.441 (0.029)	0.434 (0.037)	0.437 (0.034)	0.452 (0.035)	0.443 (0.033)
		Min	0.40	0.39	0.37	0.39	0.39	0.37
		Median	0.450	0.435	0.425	0.430	0.460	0.440
		Max	0.49	0.49	0.50	0.52	0.49	0.52

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Hematocrit [L/L]	Day 1	n	12	12	12	12	12	60
		Mean (SD)	0.430 (0.032)	0.423 (0.027)	0.418 (0.031)	0.403 (0.023)	0.435 (0.037)	0.422 (0.031)
		Min	0.38	0.38	0.37	0.37	0.38	0.37
		Median	0.430	0.420	0.420	0.405	0.440	0.420
		Max	0.49	0.48	0.45	0.45	0.48	0.49
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	0.436 (0.033)	0.428 (0.026)	0.419 (0.036)	0.409 (0.031)	0.443 (0.045)	0.427 (0.036)
		Min	0.38	0.39	0.36	0.35	0.38	0.35
		Median	0.440	0.425	0.415	0.405	0.445	0.420
		Max	0.49	0.48	0.48	0.47	0.51	0.51
	Day 8	n	12	12	12	12	12	60
		Mean (SD)	0.422 (0.035)	0.428 (0.039)	0.412 (0.034)	0.404 (0.030)	0.432 (0.038)	0.419 (0.035)
		Min	0.36	0.37	0.35	0.35	0.37	0.35
		Median	0.420	0.430	0.410	0.405	0.435	0.420
		Max	0.48	0.51	0.47	0.46	0.50	0.51

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Hematocrit [L/L]	Day 29	n	12	12	11	12	11	58
		Mean (SD)	0.440 (0.034)	0.416 (0.023)	0.420 (0.038)	0.408 (0.036)	0.421 (0.038)	0.421 (0.035)
		Min	0.36	0.39	0.34	0.34	0.37	0.34
		Median	0.450	0.410	0.420	0.410	0.410	0.415
		Max	0.48	0.46	0.49	0.47	0.49	0.49
	Day 50	n	11	12	12	12	12	59
		Mean (SD)	0.426 (0.030)	0.413 (0.025)	0.423 (0.042)	0.394 (0.023)	0.439 (0.037)	0.419 (0.035)
		Min	0.37	0.37	0.37	0.37	0.38	0.37
		Median	0.420	0.410	0.415	0.385	0.445	0.410
		Max	0.48	0.46	0.49	0.44	0.50	0.50
Hemoglobin (Blood) [mmol/L]	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	8.73 (0.77)	8.53 (0.68)	8.58 (0.89)	8.43 (0.57)	8.89 (0.80)	8.63 (0.74)
		Min	7.5	7.4	6.9	7.8	7.5	6.9
		Median	8.80	8.45	8.55	8.30	9.15	8.60
		Max	10.0	9.8	9.9	9.7	9.9	10.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Hemoglobin (Blood) [mmol/L]	Day 1	n	12	12	12	12	12	60
		Mean (SD)	8.38 (0.73)	8.08 (0.61)	8.23 (0.71)	7.93 (0.40)	8.52 (0.91)	8.23 (0.70)
		Min	7.4	7.0	7.2	7.3	7.1	7.0
		Median	8.45	8.15	8.25	7.90	8.65	8.20
		Max	9.5	9.3	9.2	8.9	9.6	9.6
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	8.49 (0.71)	8.13 (0.65)	8.25 (0.77)	7.98 (0.54)	8.66 (1.01)	8.30 (0.77)
		Min	7.4	7.2	7.0	6.9	7.1	6.9
		Median	8.50	8.00	8.15	8.05	8.80	8.10
		Max	9.8	9.4	9.5	9.0	10.2	10.2
	Day 8	n	12	12	12	12	12	60
		Mean (SD)	8.30 (0.76)	8.02 (0.73)	8.16 (0.70)	7.88 (0.60)	8.41 (0.92)	8.15 (0.75)
		Min	7.0	6.8	6.8	6.8	6.9	6.8
		Median	8.35	7.90	8.20	7.90	8.50	8.05
		Max	9.4	9.2	9.1	9.1	9.5	9.5

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Hemoglobin (Blood) [mmol/L]	Day 29	n	12	12	11	12	11	58
		Mean (SD)	8.48 (0.64)	8.19 (0.54)	8.28 (0.81)	7.82 (0.62)	8.22 (0.83)	8.20 (0.70)
		Min	7.2	7.6	6.7	6.6	7.0	6.6
		Median	8.65	7.90	8.20	7.75	8.10	8.15
		Max	9.3	9.4	9.6	8.9	9.5	9.6
	Day 50	n	11	12	12	12	12	59
		Mean (SD)	8.36 (0.67)	8.04 (0.65)	8.19 (0.81)	7.70 (0.39)	8.23 (0.83)	8.10 (0.70)
		Min	7.0	6.9	7.1	7.1	6.7	6.7
		Median	8.40	7.95	8.20	7.60	8.50	8.00
		Max	9.4	9.1	9.4	8.5	9.5	9.5
Leukocytes (Blood) [10^9/L]	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	5.05 (0.96)	5.91 (1.14)	5.52 (0.79)	5.30 (1.17)	5.18 (0.82)	5.39 (1.00)
		Min	3.5	3.9	4.3	3.4	4.0	3.4
		Median	5.30	5.95	5.40	5.45	5.10	5.45
		Max	6.4	7.8	6.8	7.3	6.6	7.8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Leukocytes (Blood) [10^9/L]	Day 1	n	12	12	12	12	12	60
		Mean (SD)	5.20 (1.22)	5.63 (1.43)	5.26 (1.31)	5.14 (1.30)	4.78 (0.80)	5.20 (1.22)
		Min	3.9	3.6	3.5	3.2	3.3	3.2
		Median	5.00	5.20	5.10	4.95	5.00	5.00
		Max	8.4	8.2	7.8	8.4	5.7	8.4
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	5.08 (0.72)	6.01 (1.24)	5.63 (0.84)	5.58 (1.17)	6.38 (1.61)	5.74 (1.20)
		Min	3.9	4.0	4.3	4.0	4.4	3.9
		Median	5.10	5.80	5.75	5.55	5.85	5.60
		Max	6.4	8.0	7.0	7.3	9.5	9.5
	Day 8	n	12	12	12	12	12	60
		Mean (SD)	5.02 (1.10)	5.93 (1.82)	5.13 (0.97)	4.51 (1.02)	4.90 (1.18)	5.10 (1.30)
		Min	3.6	3.7	3.8	2.7	2.8	2.7
		Median	4.65	5.55	5.05	4.50	4.60	4.70
		Max	7.6	9.5	7.0	6.3	7.4	9.5

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Leukocytes (Blood) [10^9/L]	Day 29	n	12	12	11	12	11	58
		Mean (SD)	5.03 (1.11)	5.40 (1.52)	5.43 (1.37)	4.76 (0.92)	4.83 (0.85)	5.09 (1.18)
		Min	3.3	3.6	3.9	3.6	3.4	3.3
		Median	4.80	5.15	4.90	5.00	4.80	4.90
		Max	7.4	8.4	8.8	6.7	6.9	8.8
	Day 50	n	11	12	12	12	12	59
		Mean (SD)	4.57 (0.76)	5.55 (1.27)	5.25 (0.96)	4.53 (0.89)	5.28 (1.52)	5.05 (1.16)
		Min	3.4	3.7	3.9	3.5	3.4	3.4
		Median	4.70	5.60	5.30	4.30	5.05	5.00
		Max	5.4	7.9	6.7	6.2	9.4	9.4
Lymphocytes (Blood) [10^9/L]	Day -30 to 0	n	12	9	12	12	12	57
		Mean (SD)	1.858 (0.438)	1.721 (0.333)	1.823 (0.285)	1.695 (0.456)	1.780 (0.395)	1.778 (0.381)
		Min	1.29	1.15	1.28	0.92	1.17	0.92
		Median	1.860	1.820	1.730	1.775	1.795	1.800
		Max	2.67	2.12	2.25	2.51	2.41	2.67

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Lymphocytes (Blood) [10^9/L]	Day 1	n	11	12	12	12	11	58
		Mean (SD)	1.807 (0.555)	1.577 (0.385)	1.678 (0.355)	1.515 (0.442)	1.618 (0.320)	1.636 (0.415)
		Min	1.26	0.91	0.90	0.81	1.21	0.81
		Median	1.740	1.550	1.755	1.590	1.560	1.605
		Max	3.20	2.16	2.18	2.21	2.40	3.20
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	1.834 (0.332)	1.612 (0.349)	1.363 (0.283)	1.197 (0.357)	1.197 (0.319)	1.440 (0.405)
		Min	1.33	1.10	0.86	0.73	0.88	0.73
		Median	1.825	1.670	1.395	1.115	1.115	1.510
		Max	2.60	2.13	1.74	1.70	1.83	2.60
	Day 8	n	12	12	11	12	11	58
		Mean (SD)	1.823 (0.422)	1.633 (0.428)	1.776 (0.288)	1.589 (0.463)	1.690 (0.362)	1.701 (0.396)
		Min	1.07	0.86	1.30	0.93	1.24	0.86
		Median	1.770	1.705	1.820	1.475	1.690	1.700
		Max	2.84	2.29	2.16	2.55	2.42	2.84

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Lymphocytes (Blood) [10^9/L]	Day 29	n	11	11	11	11	10	54
		Mean (SD)	1.879 (0.533)	1.474 (0.308)	1.783 (0.352)	1.572 (0.452)	1.810 (0.389)	1.701 (0.428)
		Min	1.35	1.05	1.29	0.93	1.28	0.93
		Median	1.830	1.440	1.810	1.550	1.760	1.715
		Max	3.10	1.94	2.33	2.26	2.60	3.10
	Day 50	n	9	12	12	12	12	57
		Mean (SD)	1.596 (0.202)	1.563 (0.329)	1.854 (0.295)	1.464 (0.368)	1.643 (0.412)	1.626 (0.349)
		Min	1.20	1.03	1.55	0.89	0.98	0.89
		Median	1.620	1.585	1.770	1.490	1.725	1.650
		Max	1.87	2.05	2.58	1.95	2.38	2.58
Lymphocytes (Blood Smear) [10^9/L]	Day -30 to 0	n	0	3	0	0	0	3
		Mean (SD)	- (-)	2.83 (1.50)	- (-)	- (-)	- (-)	2.83 (1.50)
		Min	-	1.3	-	-	-	1.3
		Median	-	2.90	-	-	-	2.90
		Max	-	4.3	-	-	-	4.3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

Program: Tfsaf_LB_2_1.sas (Page 25 of 94)

Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Lymphocytes (Blood Smear) [10^9/L]	Day 1	n	1	0	0	0	1	2
		Mean (SD)	1.40 (-)	- (-)	- (-)	- (-)	2.40 (-)	1.90 (-)
		Min	1.4	-	-	-	2.4	1.4
		Median	1.40	-	-	-	2.40	1.90
		Max	1.4	-	-	-	2.4	2.4
	Day 8	n	0	0	1	0	1	2
		Mean (SD)	- (-)	- (-)	2.50 (-)	- (-)	2.80 (-)	2.65 (-)
		Min	-	-	2.5	-	2.8	2.5
		Median	-	-	2.50	-	2.80	2.65
		Max	-	-	2.5	-	2.8	2.8
	Day 29	n	1	0	0	1	1	3
		Mean (SD)	3.00 (-)	- (-)	- (-)	3.60 (-)	4.10 (-)	3.57 (0.55)
		Min	3.0	-	-	3.6	4.1	3.0
		Median	3.00	-	-	3.60	4.10	3.60
		Max	3.0	-	-	3.6	4.1	4.1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Lymphocytes (Blood Smear) [10^9/L]	Day 50	n	2	0	0	0	0	2
		Mean (SD)	2.40 (-)	- (-)	- (-)	- (-)	- (-)	2.40 (-)
		Min	2.3	-	-	-	-	2.3
		Median	2.40	-	-	-	-	2.40
		Max	2.5	-	-	-	-	2.5
Lymphocytes/Leukocytes (Blood) [%]	Day -30 to 0	n	12	9	12	12	12	57
		Mean (SD)	36.74 (4.33)	29.68 (4.76)	33.43 (5.78)	31.90 (5.36)	34.56 (7.18)	33.45 (5.88)
		Min	29.3	22.4	24.7	26.9	26.0	22.4
		Median	36.10	29.50	33.20	30.25	32.50	33.00
		Max	43.7	37.9	45.0	44.3	46.4	46.4
	Day 1	n	11	12	12	12	11	58
		Mean (SD)	34.50 (4.51)	28.51 (5.62)	32.68 (6.45)	29.97 (7.52)	34.71 (7.81)	31.99 (6.74)
		Min	25.2	19.8	22.2	16.9	21.8	16.9
		Median	34.60	30.65	34.25	31.25	34.80	32.55
		Max	41.9	37.1	41.8	40.8	49.2	49.2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Lymphocytes/Leukocytes (Blood) [%]	Day 2	n	12	12	12	12	12	60
		Mean (SD)	36.19 (5.07)	27.16 (5.17)	24.54 (5.25)	21.33 (3.83)	19.41 (5.91)	25.73 (7.69)
		Min	28.6	20.9	13.7	13.9	12.2	12.2
		Median	35.25	25.60	25.30	21.40	18.15	24.70
		Max	44.4	38.8	30.5	27.9	33.2	44.4
	Day 8	n	12	12	11	12	11	58
		Mean (SD)	37.02 (7.78)	28.30 (6.14)	35.49 (5.18)	35.16 (5.08)	35.97 (7.84)	34.34 (7.04)
		Min	21.7	18.2	26.0	24.8	19.2	18.2
		Median	38.60	29.25	36.20	34.65	36.70	35.15
		Max	46.6	36.9	44.8	45.3	44.8	46.6
	Day 29	n	11	11	11	11	10	54
		Mean (SD)	37.53 (5.29)	29.49 (6.09)	34.46 (9.34)	34.08 (7.77)	39.13 (6.67)	34.86 (7.66)
		Min	28.2	20.6	14.8	25.0	29.1	14.8
		Median	39.40	29.00	34.80	33.40	37.15	35.15
		Max	44.3	40.1	45.1	47.7	54.1	54.1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Lymphocytes/Leukocytes (Blood) [%]	Day 50	n	9	12	12	12	12	57
		Mean (SD)	36.71 (4.76)	29.07 (6.90)	36.08 (6.97)	32.52 (7.01)	31.79 (6.64)	33.05 (6.95)
		Min	30.1	17.5	27.9	23.5	18.9	17.5
		Median	36.60	31.90	34.45	32.55	31.20	33.20
		Max	43.1	36.2	48.2	45.2	46.0	48.2
Lymphocytes/Leukocytes (Blood Smear) [%]	Day -30 to 0	n	0	3	0	0	0	3
		Mean (SD)	- (-)	47.3 (24.0)	- (-)	- (-)	- (-)	47.3 (24.0)
		Min	-	24	-	-	-	24
		Median	-	46.0	-	-	-	46.0
		Max	-	72	-	-	-	72
	Day 1	n	1	0	0	0	1	2
		Mean (SD)	27.0 (-)	- (-)	- (-)	- (-)	48.0 (-)	37.5 (-)
		Min	27	-	-	-	48	27
		Median	27.0	-	-	-	48.0	37.5
		Max	27	-	-	-	48	48

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Lymphocytes/Leukocytes (Blood Smear) [%]	Day 8	n	0	0	1	0	1	2
		Mean (SD)	- (-)	- (-)	44.0 (-)	- (-)	51.0 (-)	47.5 (-)
		Min	-	-	44	-	51	44
		Median	-	-	44.0	-	51.0	47.5
		Max	-	-	44	-	51	51
	Day 29	n	1	0	0	1	1	3
		Mean (SD)	58.0 (-)	- (-)	- (-)	54.0 (-)	60.0 (-)	57.3 (3.1)
		Min	58	-	-	54	60	54
		Median	58.0	-	-	54.0	60.0	58.0
		Max	58	-	-	54	60	60
	Day 50	n	2	0	0	0	0	2
		Mean (SD)	45.5 (-)	- (-)	- (-)	- (-)	- (-)	45.5 (-)
		Min	43	-	-	-	-	43
		Median	45.5	-	-	-	-	45.5
		Max	48	-	-	-	-	48

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Monocytes (Blood) [10^9/L]	Day -30 to 0	n	12	9	12	12	12	57
		Mean (SD)	0.404 (0.094)	0.432 (0.064)	0.472 (0.084)	0.389 (0.118)	0.478 (0.124)	0.435 (0.104)
		Min	0.27	0.32	0.32	0.22	0.32	0.22
		Median	0.390	0.450	0.470	0.375	0.465	0.440
		Max	0.61	0.50	0.61	0.60	0.76	0.76
	Day 1	n	11	12	12	12	11	58
		Mean (SD)	0.467 (0.154)	0.426 (0.082)	0.443 (0.090)	0.394 (0.074)	0.485 (0.130)	0.442 (0.110)
		Min	0.24	0.29	0.31	0.30	0.28	0.24
		Median	0.480	0.420	0.435	0.380	0.460	0.425
		Max	0.82	0.59	0.57	0.54	0.70	0.82
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	0.463 (0.110)	0.494 (0.131)	0.579 (0.117)	0.514 (0.094)	0.709 (0.178)	0.552 (0.153)
		Min	0.24	0.24	0.40	0.36	0.51	0.24
		Median	0.475	0.485	0.555	0.500	0.650	0.520
		Max	0.66	0.71	0.77	0.67	1.05	1.05

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Monocytes (Blood) [10^9/L]	Day 8	n	12	12	11	12	11	58
		Mean (SD)	0.431 (0.131)	0.447 (0.129)	0.401 (0.068)	0.367 (0.094)	0.436 (0.159)	0.416 (0.120)
		Min	0.16	0.25	0.29	0.25	0.31	0.16
		Median	0.415	0.425	0.390	0.340	0.370	0.390
		Max	0.63	0.67	0.55	0.55	0.87	0.87
	Day 29	n	11	11	11	11	10	54
		Mean (SD)	0.418 (0.116)	0.395 (0.091)	0.409 (0.131)	0.363 (0.081)	0.383 (0.074)	0.394 (0.099)
		Min	0.29	0.22	0.29	0.26	0.31	0.22
		Median	0.380	0.410	0.380	0.370	0.395	0.385
		Max	0.71	0.59	0.73	0.49	0.54	0.73
	Day 50	n	9	12	12	12	12	57
		Mean (SD)	0.374 (0.098)	0.408 (0.091)	0.432 (0.140)	0.372 (0.079)	0.518 (0.211)	0.423 (0.141)
		Min	0.16	0.24	0.11	0.26	0.36	0.11
		Median	0.370	0.400	0.440	0.365	0.450	0.410
		Max	0.50	0.58	0.71	0.53	1.08	1.08

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Monocytes (Blood Smear) [10^9/L]	Day -30 to 0	n	0	3	0	0	0	3
		Mean (SD)	- (-)	0.383 (0.235)	- (-)	- (-)	- (-)	0.383 (0.235)
		Min	-	0.18	-	-	-	0.18
		Median	-	0.330	-	-	-	0.330
		Max	-	0.64	-	-	-	0.64
	Day 1	n	1	0	0	0	1	2
		Mean (SD)	0.650 (-)	- (-)	- (-)	- (-)	0.290 (-)	0.470 (-)
		Min	0.65	-	-	-	0.29	0.29
		Median	0.650	-	-	-	0.290	0.470
		Max	0.65	-	-	-	0.29	0.65
	Day 8	n	0	0	1	0	1	2
		Mean (SD)	- (-)	- (-)	0.460 (-)	- (-)	0.320 (-)	0.390 (-)
		Min	-	-	0.46	-	0.32	0.32
		Median	-	-	0.460	-	0.320	0.390
		Max	-	-	0.46	-	0.32	0.46

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Monocytes (Blood Smear) [10^9/L]	Day 29	n	1	0	0	1	1	3
		Mean (SD)	0.570 (-)	- (-)	- (-)	0.400 (-)	0.350 (-)	0.440 (0.115)
		Min	0.57	-	-	0.40	0.35	0.35
		Median	0.570	-	-	0.400	0.350	0.400
		Max	0.57	-	-	0.40	0.35	0.57
	Day 50	n	2	0	0	0	0	2
		Mean (SD)	0.345 (-)	- (-)	- (-)	- (-)	- (-)	0.345 (-)
		Min	0.32	-	-	-	-	0.32
		Median	0.345	-	-	-	-	0.345
		Max	0.37	-	-	-	-	0.37
Monocytes/Leukocytes (Blood) [%]	Day -30 to 0	n	12	9	12	12	12	57
		Mean (SD)	8.05 (1.30)	7.70 (2.26)	8.63 (1.58)	7.41 (1.99)	9.29 (2.21)	8.24 (1.94)
		Min	6.1	4.1	5.9	5.5	6.2	4.1
		Median	7.95	6.90	8.65	6.75	8.95	8.00
		Max	10.2	11.2	11.0	11.3	12.4	12.4

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Monocytes/Leukocytes (Blood) [%]	Day 1	n	11	12	12	12	11	58
		Mean (SD)	9.00 (2.20)	7.80 (1.64)	8.56 (1.19)	7.86 (1.20)	10.09 (1.59)	8.63 (1.75)
		Min	5.4	4.4	6.6	6.1	7.1	4.4
		Median	8.90	7.70	8.60	7.75	10.10	8.60
		Max	13.1	10.4	10.8	10.2	12.2	13.1
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	9.15 (2.13)	8.42 (2.10)	10.33 (1.73)	9.41 (1.78)	11.25 (1.85)	9.71 (2.11)
		Min	5.2	4.4	7.9	6.8	8.6	4.4
		Median	9.65	8.65	10.45	9.55	11.40	9.65
		Max	12.2	11.8	13.8	11.9	14.5	14.5
	Day 8	n	12	12	11	12	11	58
		Mean (SD)	8.64 (2.47)	7.79 (2.03)	8.04 (1.37)	8.30 (1.84)	9.03 (2.01)	8.35 (1.97)
		Min	3.9	4.7	5.5	6.2	6.6	3.9
		Median	8.35	7.40	8.30	7.75	8.20	8.20
		Max	14.0	11.4	9.9	12.2	11.9	14.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Monocytes/Leukocytes (Blood) [%]	Day 29	n	11	11	11	11	10	54
		Mean (SD)	8.55 (2.17)	8.03 (2.24)	7.61 (1.79)	7.97 (1.73)	8.35 (1.64)	8.10 (1.89)
		Min	5.5	4.4	4.6	6.1	6.1	4.4
		Median	8.20	7.60	7.90	7.80	8.95	8.10
		Max	12.6	11.3	10.6	11.8	11.1	12.6
	Day 50	n	9	12	12	12	12	57
		Mean (SD)	8.70 (2.82)	7.63 (2.17)	8.20 (2.46)	8.36 (1.88)	9.70 (1.60)	8.51 (2.23)
		Min	4.4	4.6	2.8	5.8	7.2	2.8
		Median	8.10	7.55	8.30	8.45	9.60	8.30
		Max	14.0	11.6	12.6	11.6	12.6	14.0
Monocytes/Leukocytes (Blood Smear) [%]	Day -30 to 0	n	0	3	0	0	0	3
		Mean (SD)	- (-)	6.3 (3.5)	- (-)	- (-)	- (-)	6.3 (3.5)
		Min	-	3	-	-	-	3
		Median	-	6.0	-	-	-	6.0
		Max	-	10	-	-	-	10

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Monocytes/Leukocytes (Blood Smear) [%]	Day 1	n	1	0	0	0	1	2
		Mean (SD)	13.0 (-)	- (-)	- (-)	- (-)	6.0 (-)	9.5 (-)
		Min	13	-	-	-	6	6
		Median	13.0	-	-	-	6.0	9.5
		Max	13	-	-	-	6	13
	Day 8	n	0	0	1	0	1	2
		Mean (SD)	- (-)	- (-)	8.0 (-)	- (-)	6.0 (-)	7.0 (-)
		Min	-	-	8	-	6	6
		Median	-	-	8.0	-	6.0	7.0
		Max	-	-	8	-	6	8
	Day 29	n	1	0	0	1	1	3
		Mean (SD)	11.0 (-)	- (-)	- (-)	6.0 (-)	5.0 (-)	7.3 (3.2)
		Min	11	-	-	6	5	5
		Median	11.0	-	-	6.0	5.0	6.0
		Max	11	-	-	6	5	11

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Monocytes/Leukocytes (Blood Smear) [%]	Day 50	n	2	0	0	0	0	2
		Mean (SD)	6.5 (-)	- (-)	- (-)	- (-)	- (-)	6.5 (-)
		Min	6	-	-	-	-	6
		Median	6.5	-	-	-	-	6.5
		Max	7	-	-	-	-	7
Neutrophils (Blood) [10^9/L]	Day -30 to 0	n	12	9	12	12	12	57
		Mean (SD)	2.568 (0.539)	3.557 (1.113)	3.035 (0.690)	3.063 (0.792)	2.762 (0.634)	2.967 (0.795)
		Min	1.73	2.09	2.07	1.99	1.64	1.64
		Median	2.535	3.620	3.000	2.965	2.625	2.870
		Max	3.41	5.56	4.23	4.74	3.85	5.56
	Day 1	n	11	12	12	12	11	58
		Mean (SD)	2.735 (0.689)	3.428 (1.145)	2.976 (1.074)	3.072 (1.082)	2.482 (0.643)	2.950 (0.980)
		Min	1.76	1.89	1.67	1.54	1.35	1.35
		Median	2.750	3.120	2.645	2.685	2.640	2.720
		Max	3.96	5.64	5.43	5.79	3.43	5.79

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Neutrophils (Blood) [10^9/L]	Day 2	n	12	12	12	12	12	60
		Mean (SD)	2.556 (0.517)	3.677 (0.984)	3.517 (0.731)	3.717 (0.911)	4.319 (1.416)	3.557 (1.090)
		Min	1.79	2.17	2.41	2.52	2.78	1.79
		Median	2.640	3.365	3.690	3.620	3.950	3.315
		Max	3.42	5.33	5.08	5.66	6.89	6.89
	Day 8	n	12	12	11	12	11	58
		Mean (SD)	2.525 (0.991)	3.622 (1.392)	2.708 (0.804)	2.371 (0.614)	2.540 (0.946)	2.758 (1.056)
		Min	1.60	1.95	1.69	1.44	1.17	1.17
		Median	2.165	3.150	2.470	2.455	2.260	2.490
		Max	5.27	6.14	4.33	3.09	4.71	6.14
	Day 29	n	11	11	11	11	10	54
		Mean (SD)	2.464 (0.659)	3.084 (1.071)	3.037 (1.366)	2.459 (0.459)	2.246 (0.379)	2.666 (0.911)
		Min	1.44	1.65	1.73	1.64	1.75	1.44
		Median	2.340	2.960	2.750	2.370	2.240	2.485
		Max	3.48	4.98	6.64	3.33	2.84	6.64

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Neutrophils (Blood) [10^9/L]	Day 50	n	9	12	12	12	12	57
		Mean (SD)	2.213 (0.622)	3.394 (1.189)	2.725 (0.728)	2.537 (0.736)	2.930 (1.085)	2.789 (0.962)
		Min	1.44	1.83	1.72	1.59	1.96	1.44
		Median	2.270	3.050	2.670	2.380	2.790	2.710
		Max	3.07	5.49	4.00	3.87	6.05	6.05
Neutrophils (Blood Smear) [10^9/L]	Day -30 to 0	n	0	3	0	0	0	3
		Mean (SD)	- (-)	1.30 (1.30)	- (-)	- (-)	- (-)	1.30 (1.30)
		Min	-	0.5	-	-	-	0.5
		Median	-	0.60	-	-	-	0.60
		Max	-	2.8	-	-	-	2.8
	Day 1	n	1	0	0	0	1	2
		Mean (SD)	1.90 (-)	- (-)	- (-)	- (-)	1.40 (-)	1.65 (-)
		Min	1.9	-	-	-	1.4	1.4
		Median	1.90	-	-	-	1.40	1.65
		Max	1.9	-	-	-	1.4	1.9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Neutrophils (Blood Smear) [10^9/L]	Day 8	n	0	0	1	0	1	2
		Mean (SD)	- (-)	- (-)	1.90 (-)	- (-)	1.10 (-)	1.50 (-)
		Min	-	-	1.9	-	1.1	1.1
		Median	-	-	1.90	-	1.10	1.50
		Max	-	-	1.9	-	1.1	1.9
	Day 29	n	1	0	0	1	1	3
		Mean (SD)	1.30 (-)	- (-)	- (-)	2.40 (-)	1.90 (-)	1.87 (0.55)
		Min	1.3	-	-	2.4	1.9	1.3
		Median	1.30	-	-	2.40	1.90	1.90
		Max	1.3	-	-	2.4	1.9	2.4
	Day 50	n	2	0	0	0	0	2
		Mean (SD)	1.90 (-)	- (-)	- (-)	- (-)	- (-)	1.90 (-)
		Min	1.9	-	-	-	-	1.9
		Median	1.90	-	-	-	-	1.90
		Max	1.9	-	-	-	-	1.9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Neutrophils/Leukocytes (Blood) [%]	Day -30 to 0	n	12	9	12	12	12	57
		Mean (SD)	50.92 (5.34)	59.28 (6.09)	54.55 (6.28)	57.59 (5.29)	52.89 (6.17)	54.82 (6.37)
		Min	41.6	53.2	41.4	46.2	41.1	41.1
		Median	52.30	59.70	55.25	58.35	55.00	54.60
		Max	60.7	71.3	63.1	65.9	60.8	71.3
	Day 1	n	11	12	12	12	11	58
		Mean (SD)	52.42 (6.07)	59.96 (6.19)	55.49 (7.30)	58.88 (8.67)	51.52 (6.39)	55.78 (7.56)
		Min	41.0	52.5	47.5	48.1	40.7	40.7
		Median	51.50	58.80	52.25	57.60	51.10	54.25
		Max	63.4	73.2	69.6	73.5	60.1	73.5
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	50.09 (6.12)	60.67 (5.72)	62.13 (5.24)	66.42 (4.62)	66.76 (6.84)	61.21 (8.25)
		Min	41.1	50.6	54.7	60.7	50.5	41.1
		Median	50.45	62.05	62.75	65.00	67.55	62.80
		Max	60.0	72.0	72.6	77.5	75.5	77.5

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Neutrophils/Leukocytes (Blood) [%]	Day 8	n	12	12	11	12	11	58
		Mean (SD)	49.43 (9.60)	59.86 (6.13)	52.59 (5.76)	52.44 (6.10)	51.14 (6.86)	53.13 (7.72)
		Min	37.7	51.9	43.8	42.8	41.8	37.7
		Median	44.85	58.40	52.10	52.75	53.10	53.25
		Max	69.3	69.3	61.8	64.1	63.6	69.3
	Day 29	n	11	11	11	11	10	54
		Mean (SD)	49.05 (6.71)	58.85 (8.12)	54.10 (9.44)	53.87 (7.11)	48.61 (5.51)	52.97 (8.17)
		Min	38.3	45.8	43.0	43.2	37.5	37.5
		Median	48.00	59.00	52.00	55.40	49.65	51.95
		Max	62.2	69.2	75.4	64.4	55.7	75.4
	Day 50	n	9	12	12	12	12	57
		Mean (SD)	49.57 (6.34)	59.78 (8.23)	51.30 (6.10)	55.36 (8.28)	54.90 (6.25)	54.42 (7.73)
		Min	39.8	49.4	40.0	43.7	41.6	39.8
		Median	49.80	56.45	53.25	57.10	55.95	54.40
		Max	58.0	73.7	61.6	66.4	64.4	73.7

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Neutrophils/Leukocytes (Blood Smear) [%]	Day -30 to 0	n	0	3	0	0	0	3
		Mean (SD)	- (-)	22.7 (24.5)	- (-)	- (-)	- (-)	22.7 (24.5)
		Min	-	8	-	-	-	8
		Median	-	9.0	-	-	-	9.0
		Max	-	51	-	-	-	51
	Day 1	n	1	0	0	0	1	2
		Mean (SD)	38.0 (-)	- (-)	- (-)	- (-)	28.0 (-)	33.0 (-)
		Min	38	-	-	-	28	28
		Median	38.0	-	-	-	28.0	33.0
		Max	38	-	-	-	28	38
	Day 8	n	0	0	1	0	1	2
		Mean (SD)	- (-)	- (-)	34.0 (-)	- (-)	20.0 (-)	27.0 (-)
		Min	-	-	34	-	20	20
		Median	-	-	34.0	-	20.0	27.0
		Max	-	-	34	-	20	34

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Neutrophils/Leukocytes (Blood Smear) [%]	Day 29	n	1	0	0	1	1	3
		Mean (SD)	25.0 (-)	- (-)	- (-)	36.0 (-)	28.0 (-)	29.7 (5.7)
		Min	25	-	-	36	28	25
		Median	25.0	-	-	36.0	28.0	28.0
		Max	25	-	-	36	28	36
	Day 50	n	2	0	0	0	0	2
		Mean (SD)	35.5 (-)	- (-)	- (-)	- (-)	- (-)	35.5 (-)
		Min	35	-	-	-	-	35
		Median	35.5	-	-	-	-	35.5
		Max	36	-	-	-	-	36
Platelets [10^9/L]	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	219.7 (32.4)	265.1 (50.2)	237.5 (50.9)	249.7 (56.5)	218.3 (33.9)	238.1 (47.7)
		Min	184	199	162	156	179	156
		Median	212.0	251.5	233.5	252.5	213.0	235.5
		Max	283	361	348	330	286	361

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Platelets [10^9/L]	Day 1	n	12	12	12	12	12	60
		Mean (SD)	208.3 (23.1)	254.1 (35.1)	218.0 (51.1)	240.9 (57.5)	204.0 (23.8)	225.1 (43.8)
		Min	155	200	136	136	167	136
		Median	210.0	239.5	220.5	243.5	204.5	222.0
		Max	241	307	308	326	243	326
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	211.5 (25.2)	256.4 (32.6)	218.6 (46.9)	225.5 (52.3)	195.8 (26.9)	221.6 (42.2)
		Min	157	204	140	143	160	140
		Median	214.0	253.5	209.0	224.5	194.0	218.0
		Max	256	309	298	302	237	309
	Day 8	n	12	12	12	12	12	60
		Mean (SD)	212.3 (23.6)	266.2 (46.5)	238.3 (52.3)	244.9 (50.8)	212.6 (36.1)	234.9 (46.6)
		Min	165	177	162	160	170	160
		Median	211.0	257.5	246.0	241.5	201.0	232.5
		Max	246	333	346	320	286	346

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Platelets [10^9/L]	Day 29	n	12	12	11	12	11	58
		Mean (SD)	207.7 (25.2)	260.3 (35.8)	223.4 (52.3)	244.2 (64.3)	205.5 (37.1)	228.7 (48.5)
		Min	164	204	157	143	152	143
		Median	209.5	258.5	222.0	251.0	209.0	227.0
		Max	242	333	327	349	279	349
	Day 50	n	11	12	12	12	12	59
		Mean (SD)	210.3 (31.7)	252.3 (48.0)	220.5 (43.9)	236.3 (53.3)	203.2 (27.0)	224.7 (44.5)
		Min	173	179	155	157	165	155
		Median	207.0	246.0	227.0	225.5	202.5	224.0
		Max	278	316	312	321	255	321

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Basophils (Blood) [10^9/L]	Day -30 to 0	n	12	12	12	36	93
		Mean (SD)	0.045 (0.012)	0.048 (0.018)	0.044 (0.018)	0.046 (0.016)	0.043 (0.018)
		Min	0.03	0.01	0.02	0.01	0.01
		Median	0.050	0.050	0.045	0.050	0.040
		Max	0.06	0.08	0.08	0.08	0.10
	Day 1	n	12	12	12	36	94
		Mean (SD)	0.047 (0.019)	0.049 (0.024)	0.046 (0.018)	0.047 (0.020)	0.044 (0.019)
		Min	0.02	0.01	0.03	0.01	0.01
		Median	0.045	0.050	0.040	0.045	0.040
		Max	0.08	0.09	0.09	0.09	0.09
	Day 2	n	12	12	12	36	96
		Mean (SD)	0.044 (0.016)	0.042 (0.018)	0.035 (0.017)	0.040 (0.017)	0.040 (0.019)
		Min	0.02	0.01	0.02	0.01	0.00
		Median	0.040	0.040	0.030	0.040	0.040
		Max	0.06	0.07	0.08	0.08	0.12

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Basophils (Blood) [10^9/L]	Day 8	n	11	12	12	35	93
		Mean (SD)	0.040 (0.012)	0.048 (0.018)	0.037 (0.014)	0.041 (0.015)	0.040 (0.016)
		Min	0.02	0.01	0.02	0.01	0.00
		Median	0.040	0.055	0.035	0.040	0.040
		Max	0.06	0.07	0.07	0.07	0.09
	Day 29	n	12	12	12	36	90
		Mean (SD)	0.048 (0.019)	0.047 (0.016)	0.041 (0.014)	0.045 (0.016)	0.041 (0.017)
		Min	0.02	0.02	0.03	0.02	0.01
		Median	0.040	0.050	0.035	0.040	0.040
		Max	0.09	0.07	0.07	0.09	0.09
	Day 50	n	10	11	12	33	90
		Mean (SD)	0.051 (0.018)	0.050 (0.025)	0.042 (0.014)	0.047 (0.019)	0.042 (0.018)
		Min	0.02	0.01	0.02	0.01	0.01
		Median	0.050	0.050	0.040	0.050	0.040
		Max	0.08	0.09	0.07	0.09	0.10

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Basophils (Blood Smear) [10^9/L]	Day -30 to 0	n	0	0	0	0	3
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	0.020 (0.035)
		Min	-	-	-	-	0.00
		Median	-	-	-	-	0.000
		Max	-	-	-	-	0.06
	Day 1	n	0	0	0	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	0.050 (-)
		Min	-	-	-	-	0.00
		Median	-	-	-	-	0.050
		Max	-	-	-	-	0.10
	Day 8	n	1	0	0	1	3
		Mean (SD)	0.100 (-)	- (-)	- (-)	0.100 (-)	0.033 (0.058)
		Min	0.10	-	-	0.10	0.00
		Median	0.100	-	-	0.100	0.000
		Max	0.10	-	-	0.10	0.10

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Basophils (Blood Smear) [10^9/L]	Day 29	n	0	0	0	0	3
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	0.083 (0.104)
		Min	-	-	-	-	0.00
		Median	-	-	-	-	0.050
		Max	-	-	-	-	0.20
	Day 50	n	0	0	0	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	0.185 (-)
		Min	-	-	-	-	0.16
		Median	-	-	-	-	0.185
		Max	-	-	-	-	0.21
Basophils/Leukocytes (Blood) [%]	Day -30 to 0	n	12	12	12	36	93
		Mean (SD)	0.79 (0.24)	0.81 (0.22)	0.83 (0.36)	0.81 (0.27)	0.79 (0.33)
		Min	0.4	0.3	0.3	0.3	0.2
		Median	0.80	0.80	0.80	0.80	0.80
		Max	1.2	1.2	1.4	1.4	1.9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Basophils/Leukocytes (Blood) [%]	Day 1	n	12	12	12	36	94
		Mean (SD)	0.83 (0.33)	0.94 (0.48)	0.79 (0.26)	0.85 (0.36)	0.84 (0.38)
		Min	0.4	0.3	0.6	0.3	0.2
		Median	0.75	0.85	0.65	0.75	0.80
		Max	1.6	1.6	1.4	1.6	1.6
	Day 2	n	12	12	12	36	96
		Mean (SD)	0.78 (0.22)	0.68 (0.28)	0.63 (0.31)	0.69 (0.27)	0.70 (0.33)
		Min	0.3	0.2	0.3	0.2	0.0
		Median	0.85	0.60	0.50	0.70	0.70
		Max	1.0	1.3	1.2	1.3	2.1
	Day 8	n	11	12	12	35	93
		Mean (SD)	0.78 (0.25)	0.83 (0.32)	0.68 (0.28)	0.77 (0.28)	0.80 (0.34)
		Min	0.3	0.3	0.3	0.3	0.0
		Median	0.80	0.90	0.65	0.80	0.80
		Max	1.1	1.3	1.2	1.3	1.9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Basophils/Leukocytes (Blood) [%]	Day 29	n	12	12	12	36	90
		Mean (SD)	0.89 (0.33)	0.88 (0.29)	0.78 (0.16)	0.85 (0.27)	0.82 (0.32)
		Min	0.4	0.5	0.6	0.4	0.2
		Median	0.90	0.85	0.75	0.80	0.80
		Max	1.8	1.4	1.1	1.8	1.9
	Day 50	n	10	11	12	33	90
		Mean (SD)	0.91 (0.26)	0.84 (0.41)	0.83 (0.27)	0.86 (0.31)	0.82 (0.32)
		Min	0.4	0.3	0.4	0.3	0.2
		Median	0.85	0.90	0.80	0.80	0.80
		Max	1.4	1.5	1.4	1.5	1.5
Basophils/Leukocytes (Blood Smear) [%]	Day -30 to 0	n	0	0	0	0	3
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	0.3 (0.6)
		Min	-	-	-	-	0
		Median	-	-	-	-	0.0
		Max	-	-	-	-	1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Basophils/Leukocytes (Blood Smear) [%]	Day 1	n	0	0	0	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.0 (-)
		Min	-	-	-	-	0
		Median	-	-	-	-	1.0
		Max	-	-	-	-	2
	Day 8	n	1	0	0	1	3
		Mean (SD)	2.0 (-)	- (-)	- (-)	2.0 (-)	0.7 (1.2)
		Min	2	-	-	2	0
		Median	2.0	-	-	2.0	0.0
		Max	2	-	-	2	2
	Day 29	n	0	0	0	0	3
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.3 (1.5)
		Min	-	-	-	-	0
		Median	-	-	-	-	1.0
		Max	-	-	-	-	3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Basophils/Leukocytes (Blood Smear) [%]	Day 50	n	0	0	0	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	3.5 (-)
		Min	-	-	-	-	3
		Median	-	-	-	-	3.5
		Max	-	-	-	-	4
Eosinophils (Blood) [10^9/L]	Day -30 to 0	n	12	12	12	36	93
		Mean (SD)	0.132 (0.084)	0.119 (0.082)	0.136 (0.063)	0.129 (0.075)	0.137 (0.082)
		Min	0.00	0.04	0.05	0.00	0.00
		Median	0.100	0.095	0.135	0.105	0.120
		Max	0.27	0.34	0.24	0.34	0.41
	Day 1	n	12	12	12	36	94
		Mean (SD)	0.113 (0.068)	0.103 (0.056)	0.125 (0.067)	0.114 (0.063)	0.131 (0.082)
		Min	0.00	0.03	0.02	0.00	0.00
		Median	0.110	0.100	0.125	0.100	0.100
		Max	0.23	0.21	0.24	0.24	0.47

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Eosinophils (Blood) [10^9/L]	Day 2	n	12	12	12	36	96
		Mean (SD)	0.132 (0.077)	0.117 (0.066)	0.124 (0.082)	0.124 (0.073)	0.139 (0.084)
		Min	0.00	0.04	0.03	0.00	0.00
		Median	0.110	0.105	0.115	0.110	0.120
		Max	0.29	0.29	0.30	0.30	0.38
	Day 8	n	11	12	12	35	93
		Mean (SD)	0.139 (0.089)	0.144 (0.062)	0.158 (0.083)	0.147 (0.077)	0.160 (0.095)
		Min	0.00	0.05	0.03	0.00	0.00
		Median	0.110	0.155	0.150	0.150	0.140
		Max	0.29	0.29	0.27	0.29	0.43
	Day 29	n	12	12	12	36	90
		Mean (SD)	0.149 (0.094)	0.136 (0.084)	0.153 (0.080)	0.146 (0.084)	0.155 (0.095)
		Min	0.00	0.04	0.02	0.00	0.00
		Median	0.135	0.120	0.180	0.135	0.130
		Max	0.40	0.36	0.27	0.40	0.44

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Eosinophils (Blood) [10^9/L]	Day 50	n	10	11	12	33	90
		Mean (SD)	0.160 (0.088)	0.147 (0.104)	0.167 (0.093)	0.158 (0.093)	0.159 (0.100)
		Min	0.09	0.06	0.06	0.06	0.02
		Median	0.135	0.110	0.160	0.130	0.140
		Max	0.38	0.43	0.35	0.43	0.47
Eosinophils (Blood Smear) [10^9/L]	Day -30 to 0	n	0	0	0	0	3
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	0.193 (0.135)
		Min	-	-	-	-	0.06
		Median	-	-	-	-	0.190
		Max	-	-	-	-	0.33
	Day 1	n	0	0	0	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	0.075 (-)
		Min	-	-	-	-	0.05
		Median	-	-	-	-	0.075
		Max	-	-	-	-	0.10

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Eosinophils (Blood Smear) [10^9/L]	Day 8	n	1	0	0	1	3
		Mean (SD)	0.050 (-)	- (-)	- (-)	0.050 (-)	0.110 (0.104)
		Min	0.05	-	-	0.05	0.05
		Median	0.050	-	-	0.050	0.050
		Max	0.05	-	-	0.05	0.23
	Day 29	n	0	0	0	0	3
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	0.040 (0.036)
		Min	-	-	-	-	0.00
		Median	-	-	-	-	0.050
		Max	-	-	-	-	0.07
	Day 50	n	0	0	0	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	0.080 (-)
		Min	-	-	-	-	0.05
		Median	-	-	-	-	0.080
		Max	-	-	-	-	0.11

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Eosinophils/Leukocytes (Blood) [%]	Day -30 to 0	n	12	12	12	36	93
		Mean (SD)	2.27 (1.35)	1.95 (0.97)	2.54 (1.27)	2.25 (1.20)	2.53 (1.49)
		Min	0.0	0.8	1.1	0.0	0.0
		Median	1.65	1.90	2.15	1.90	2.10
		Max	4.5	4.3	4.9	4.9	9.0
	Day 1	n	12	12	12	36	94
		Mean (SD)	2.01 (1.27)	1.91 (0.92)	2.18 (1.20)	2.03 (1.11)	2.49 (1.56)
		Min	0.0	0.7	0.4	0.0	0.0
		Median	1.75	1.65	2.30	1.85	2.10
		Max	4.6	3.7	4.6	4.6	8.9
	Day 2	n	12	12	12	36	96
		Mean (SD)	2.35 (1.28)	1.88 (0.80)	2.19 (1.28)	2.14 (1.13)	2.46 (1.49)
		Min	0.0	0.8	0.5	0.0	0.0
		Median	2.00	1.80	2.15	2.00	2.10
		Max	4.9	3.3	4.3	4.9	7.6

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Eosinophils/Leukocytes (Blood) [%]	Day 8	n	11	12	12	35	93
		Mean (SD)	2.65 (1.56)	2.64 (1.22)	2.98 (1.69)	2.76 (1.46)	3.13 (1.88)
		Min	0.0	1.1	0.7	0.0	0.0
		Median	2.60	2.30	3.00	2.60	2.80
		Max	5.4	5.2	6.7	6.7	9.6
	Day 29	n	12	12	12	36	90
		Mean (SD)	2.85 (1.93)	2.53 (1.37)	3.09 (1.71)	2.82 (1.65)	3.09 (1.88)
		Min	0.0	0.9	0.3	0.0	0.0
		Median	2.40	2.45	3.50	2.50	2.60
		Max	8.2	6.1	6.3	8.2	9.2
	Day 50	n	10	11	12	33	90
		Mean (SD)	2.91 (1.47)	2.43 (1.33)	3.18 (1.46)	2.85 (1.41)	3.09 (1.83)
		Min	1.3	1.2	1.5	1.2	0.4
		Median	2.55	2.10	3.10	2.60	2.65
		Max	6.4	5.8	6.0	6.4	9.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Eosinophils/Leukocytes (Blood Smear) [%]	Day -30 to 0	n	0	0	0	0	3
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	3.3 (2.5)
		Min	-	-	-	-	1
		Median	-	-	-	-	3.0
		Max	-	-	-	-	6
	Day 1	n	0	0	0	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.5 (-)
		Min	-	-	-	-	1
		Median	-	-	-	-	1.5
		Max	-	-	-	-	2
	Day 8	n	1	0	0	1	3
		Mean (SD)	1.0 (-)	- (-)	- (-)	1.0 (-)	2.0 (1.7)
		Min	1	-	-	1	1
		Median	1.0	-	-	1.0	1.0
		Max	1	-	-	1	4

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Eosinophils/Leukocytes (Blood Smear) [%]	Day 29	n	0	0	0	0	3
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	0.7 (0.6)
		Min	-	-	-	-	0
		Median	-	-	-	-	1.0
		Max	-	-	-	-	1
	Day 50	n	0	0	0	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.5 (-)
		Min	-	-	-	-	1
		Median	-	-	-	-	1.5
		Max	-	-	-	-	2
Erythrocytes (Blood) [10^{12}/L]	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	4.68 (0.42)	4.43 (0.37)	4.48 (0.33)	4.53 (0.38)	4.62 (0.38)
		Min	4.2	3.9	3.9	3.9	3.9
		Median	4.75	4.35	4.40	4.40	4.60
		Max	5.5	5.1	5.1	5.5	5.6

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Erythrocytes (Blood) [10^{12}/L]	Day 1	n	12	12	12	36	96
		Mean (SD)	4.56 (0.37)	4.27 (0.37)	4.53 (0.31)	4.45 (0.37)	4.45 (0.38)
		Min	4.1	3.7	4.1	3.7	3.7
		Median	4.65	4.20	4.40	4.40	4.40
		Max	5.1	4.8	5.2	5.2	5.2
	Day 2	n	12	12	12	36	96
		Mean (SD)	4.48 (0.41)	4.38 (0.36)	4.35 (0.46)	4.40 (0.40)	4.46 (0.40)
		Min	4.0	3.7	3.5	3.5	3.5
		Median	4.60	4.35	4.30	4.40	4.50
		Max	5.2	4.9	5.2	5.2	5.3
	Day 8	n	12	12	12	36	96
		Mean (SD)	4.49 (0.38)	4.28 (0.40)	4.34 (0.47)	4.37 (0.42)	4.40 (0.40)
		Min	4.0	3.7	3.8	3.7	3.5
		Median	4.60	4.20	4.35	4.40	4.40
		Max	5.1	5.2	5.2	5.2	5.2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Erythrocytes (Blood) [10^{12}/L]	Day 29	n	12	12	12	36	94
		Mean (SD)	4.64 (0.39)	4.32 (0.37)	4.50 (0.46)	4.49 (0.42)	4.47 (0.39)
		Min	4.0	3.6	3.7	3.6	3.4
		Median	4.75	4.30	4.50	4.50	4.50
		Max	5.4	4.9	5.4	5.4	5.4
	Day 50	n	10	11	12	33	92
		Mean (SD)	4.44 (0.44)	4.32 (0.43)	4.32 (0.39)	4.35 (0.41)	4.37 (0.37)
		Min	3.8	3.6	3.7	3.6	3.6
		Median	4.55	4.30	4.25	4.30	4.35
		Max	5.1	5.1	5.1	5.1	5.2
Hematocrit [L/L]	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	0.434 (0.032)	0.458 (0.033)	0.415 (0.029)	0.436 (0.035)	0.440 (0.034)
		Min	0.38	0.41	0.36	0.36	0.36
		Median	0.440	0.460	0.420	0.435	0.440
		Max	0.48	0.50	0.46	0.50	0.52

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Hematocrit [L/L]	Day 1	n	12	12	12	36	96
		Mean (SD)	0.427 (0.035)	0.412 (0.031)	0.416 (0.025)	0.418 (0.030)	0.420 (0.031)
		Min	0.37	0.36	0.38	0.36	0.36
		Median	0.415	0.415	0.410	0.410	0.420
		Max	0.49	0.47	0.46	0.49	0.49
	Day 2	n	12	12	12	36	96
		Mean (SD)	0.418 (0.034)	0.422 (0.033)	0.399 (0.033)	0.413 (0.034)	0.422 (0.035)
		Min	0.36	0.36	0.36	0.36	0.35
		Median	0.420	0.425	0.395	0.410	0.420
		Max	0.47	0.47	0.46	0.47	0.51
	Day 8	n	12	12	12	36	96
		Mean (SD)	0.418 (0.031)	0.412 (0.034)	0.399 (0.039)	0.410 (0.035)	0.416 (0.035)
		Min	0.36	0.36	0.34	0.34	0.34
		Median	0.425	0.405	0.400	0.410	0.415
		Max	0.46	0.48	0.46	0.48	0.51

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Hematocrit [L/L]	Day 29	n	12	12	12	36	94
		Mean (SD)	0.434 (0.031)	0.418 (0.033)	0.413 (0.036)	0.422 (0.034)	0.421 (0.034)
		Min	0.39	0.35	0.37	0.35	0.34
		Median	0.440	0.425	0.410	0.420	0.420
		Max	0.48	0.46	0.48	0.48	0.49
	Day 50	n	10	11	12	33	92
		Mean (SD)	0.414 (0.035)	0.413 (0.038)	0.396 (0.028)	0.407 (0.034)	0.415 (0.035)
		Min	0.36	0.35	0.36	0.35	0.35
		Median	0.420	0.420	0.390	0.410	0.410
		Max	0.46	0.48	0.45	0.48	0.50
Hemoglobin (Blood) [mmol/L]	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	8.88 (0.66)	8.49 (0.67)	8.48 (0.67)	8.62 (0.67)	8.63 (0.71)
		Min	7.9	7.5	7.2	7.2	6.9
		Median	8.80	8.45	8.65	8.65	8.60
		Max	9.9	9.6	9.2	9.9	10.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Hemoglobin (Blood) [mmol/L]	Day 1	n	12	12	12	36	96
		Mean (SD)	8.70 (0.71)	8.19 (0.60)	8.57 (0.58)	8.49 (0.65)	8.33 (0.69)
		Min	7.7	7.1	7.6	7.1	7.0
		Median	8.40	8.20	8.70	8.40	8.30
		Max	10.0	9.4	9.4	10.0	10.0
	Day 2	n	12	12	12	36	96
		Mean (SD)	8.53 (0.72)	8.37 (0.65)	8.23 (0.73)	8.38 (0.69)	8.33 (0.74)
		Min	7.5	7.2	7.4	7.2	6.9
		Median	8.25	8.50	8.15	8.35	8.20
		Max	9.7	9.6	9.5	9.7	10.2
	Day 8	n	12	12	12	36	96
		Mean (SD)	8.57 (0.60)	8.18 (0.69)	8.22 (0.87)	8.32 (0.73)	8.22 (0.74)
		Min	7.6	7.1	6.8	6.8	6.8
		Median	8.65	8.05	8.25	8.25	8.10
		Max	9.5	9.6	9.5	9.6	9.6

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Hemoglobin (Blood) [mmol/L]	Day 29	n	12	12	12	36	94
		Mean (SD)	8.80 (0.69)	8.23 (0.67)	8.44 (0.85)	8.49 (0.76)	8.31 (0.74)
		Min	7.7	6.9	7.3	6.9	6.6
		Median	8.75	8.35	8.40	8.60	8.20
		Max	9.8	9.2	10.2	10.2	10.2
	Day 50	n	10	11	12	33	92
		Mean (SD)	8.45 (0.75)	8.24 (0.80)	8.13 (0.67)	8.26 (0.73)	8.16 (0.71)
		Min	7.3	6.8	7.3	6.8	6.7
		Median	8.35	8.40	8.10	8.20	8.15
		Max	9.5	9.5	9.3	9.5	9.5
Leukocytes (Blood) [10^9/L]	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	5.84 (1.43)	5.88 (1.21)	5.49 (1.23)	5.74 (1.27)	5.52 (1.12)
		Min	3.4	3.8	3.7	3.4	3.4
		Median	5.85	6.15	5.20	5.60	5.50
		Max	8.9	7.8	7.9	8.9	8.9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Leukocytes (Blood) [10^9/L]	Day 1	n	12	12	12	36	96
		Mean (SD)	5.69 (1.01)	5.34 (1.29)	5.83 (1.22)	5.62 (1.16)	5.36 (1.21)
		Min	4.2	3.4	3.9	3.4	3.2
		Median	5.40	5.55	5.50	5.45	5.15
		Max	7.5	7.4	8.1	8.1	8.4
	Day 2	n	12	12	12	36	96
		Mean (SD)	5.68 (1.12)	6.08 (1.47)	5.74 (1.23)	5.83 (1.26)	5.77 (1.22)
		Min	3.9	4.5	3.8	3.8	3.8
		Median	5.95	5.85	6.15	6.00	5.70
		Max	7.7	9.6	7.1	9.6	9.6
	Day 8	n	12	12	12	36	96
		Mean (SD)	5.30 (1.24)	5.71 (1.71)	5.49 (1.57)	5.50 (1.49)	5.25 (1.38)
		Min	3.6	2.9	3.6	2.9	2.7
		Median	5.30	5.55	5.40	5.40	4.85
		Max	7.5	9.5	7.7	9.5	9.5

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Leukocytes (Blood) [10^9/L]	Day 29	n	12	12	12	36	94
		Mean (SD)	5.37 (0.91)	5.38 (1.20)	5.18 (1.17)	5.31 (1.07)	5.17 (1.14)
		Min	3.7	3.6	3.9	3.6	3.3
		Median	5.35	5.35	5.10	5.35	5.00
		Max	7.0	7.6	7.6	7.6	8.8
	Day 50	n	10	11	12	33	92
		Mean (SD)	5.63 (1.43)	5.90 (1.37)	5.04 (0.93)	5.51 (1.26)	5.21 (1.21)
		Min	3.2	3.4	3.7	3.2	3.2
		Median	6.00	6.00	5.10	5.70	5.20
		Max	7.6	7.9	6.2	7.9	9.4
Lymphocytes (Blood) [10^9/L]	Day -30 to 0	n	12	12	12	36	93
		Mean (SD)	1.660 (0.488)	1.962 (0.715)	1.494 (0.453)	1.705 (0.582)	1.750 (0.467)
		Min	1.09	0.88	0.95	0.88	0.88
		Median	1.490	1.735	1.405	1.625	1.720
		Max	2.43	3.39	2.41	3.39	3.39

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Lymphocytes (Blood) [10^9/L]	Day 1	n	12	12	12	36	94
		Mean (SD)	1.517 (0.373)	1.763 (0.810)	1.491 (0.451)	1.590 (0.574)	1.619 (0.480)
		Min	0.93	0.53	0.81	0.53	0.53
		Median	1.495	1.635	1.445	1.510	1.565
		Max	2.01	3.83	2.33	3.83	3.83
	Day 2	n	12	12	12	36	96
		Mean (SD)	1.407 (0.391)	1.558 (0.541)	0.988 (0.267)	1.318 (0.472)	1.394 (0.433)
		Min	0.81	0.78	0.72	0.72	0.72
		Median	1.495	1.445	0.860	1.290	1.390
		Max	2.18	2.70	1.48	2.70	2.70
	Day 8	n	11	12	12	35	93
		Mean (SD)	1.637 (0.447)	1.958 (0.784)	1.662 (0.540)	1.755 (0.611)	1.722 (0.486)
		Min	0.99	0.80	0.86	0.80	0.80
		Median	1.640	1.855	1.600	1.680	1.700
		Max	2.33	3.43	2.63	3.43	3.43

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Lymphocytes (Blood) [10^9/L]	Day 29	n	12	12	12	36	90
		Mean (SD)	1.612 (0.355)	1.798 (0.494)	1.742 (0.616)	1.717 (0.492)	1.708 (0.452)
		Min	0.95	0.78	1.20	0.78	0.78
		Median	1.645	1.780	1.665	1.680	1.705
		Max	2.08	2.67	3.53	3.53	3.53
	Day 50	n	10	11	12	33	90
		Mean (SD)	1.748 (0.543)	1.957 (0.599)	1.555 (0.426)	1.748 (0.535)	1.670 (0.428)
		Min	0.95	0.99	0.91	0.91	0.89
		Median	1.585	1.940	1.585	1.640	1.645
		Max	2.88	2.97	2.37	2.97	2.97
Lymphocytes (Blood Smear) [10^9/L]	Day -30 to 0	n	0	0	0	0	3
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	2.83 (1.50)
		Min	-	-	-	-	1.3
		Median	-	-	-	-	2.90
		Max	-	-	-	-	4.3

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Lymphocytes (Blood Smear) [10^9/L]	Day 1	n	0	0	0	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.90 (-)
		Min	-	-	-	-	1.4
		Median	-	-	-	-	1.90
		Max	-	-	-	-	2.4
	Day 8	n	1	0	0	1	3
		Mean (SD)	1.20 (-)	- (-)	- (-)	1.20 (-)	2.17 (0.85)
		Min	1.2	-	-	1.2	1.2
		Median	1.20	-	-	1.20	2.50
		Max	1.2	-	-	1.2	2.8
	Day 29	n	0	0	0	0	3
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	3.57 (0.55)
		Min	-	-	-	-	3.0
		Median	-	-	-	-	3.60
		Max	-	-	-	-	4.1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Lymphocytes (Blood Smear) [10^9/L]	Day 50	n	0	0	0	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	2.40 (-)
		Min	-	-	-	-	2.3
		Median	-	-	-	-	2.40
		Max	-	-	-	-	2.5
Lymphocytes/Leukocytes (Blood) [%]	Day -30 to 0	n	12	12	12	36	93
		Mean (SD)	28.84 (6.64)	33.21 (9.35)	27.60 (6.84)	29.88 (7.87)	32.07 (6.91)
		Min	20.1	21.9	14.8	14.8	14.8
		Median	28.10	31.50	29.85	29.25	30.90
		Max	40.1	49.9	37.0	49.9	49.9
	Day 1	n	12	12	12	36	94
		Mean (SD)	27.03 (6.90)	32.54 (10.47)	26.43 (8.05)	28.67 (8.81)	30.72 (7.73)
		Min	18.3	15.5	10.0	10.0	10.0
		Median	24.60	31.25	26.20	26.70	31.80
		Max	38.0	51.8	38.2	51.8	51.8

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Lymphocytes/Leukocytes (Blood) [%]	Day 2	n	12	12	12	36	96
		Mean (SD)	24.89 (5.67)	26.06 (8.55)	17.58 (4.31)	22.84 (7.31)	24.64 (7.64)
		Min	17.9	16.5	10.7	10.7	10.7
		Median	24.80	22.75	18.65	21.15	24.05
		Max	35.2	44.2	25.3	44.2	44.4
	Day 8	n	11	12	12	35	93
		Mean (SD)	31.21 (7.42)	34.12 (8.87)	31.88 (10.29)	32.44 (8.80)	33.62 (7.76)
		Min	22.1	23.8	11.2	11.2	11.2
		Median	29.70	30.45	30.75	30.50	32.90
		Max	44.8	50.4	44.0	50.4	50.4
	Day 29	n	12	12	12	36	90
		Mean (SD)	30.41 (7.06)	33.70 (7.73)	33.73 (7.53)	32.61 (7.40)	33.96 (7.60)
		Min	21.6	21.8	19.1	19.1	14.8
		Median	28.80	32.35	32.50	31.65	33.60
		Max	45.0	45.3	46.5	46.5	54.1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Lymphocytes/Leukocytes (Blood) [%]	Day 50	n	10	11	12	33	90
		Mean (SD)	32.12 (9.92)	33.35 (7.65)	31.44 (8.87)	32.28 (8.58)	32.77 (7.55)
		Min	18.9	20.9	16.3	16.3	16.3
		Median	30.05	30.70	28.90	30.50	32.45
		Max	50.2	45.0	46.2	50.2	50.2
Lymphocytes/Leukocytes (Blood Smear) [%]	Day -30 to 0	n	0	0	0	0	3
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	47.3 (24.0)
		Min	-	-	-	-	24
		Median	-	-	-	-	46.0
		Max	-	-	-	-	72
	Day 1	n	0	0	0	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	37.5 (-)
		Min	-	-	-	-	27
		Median	-	-	-	-	37.5
		Max	-	-	-	-	48

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Lymphocytes/Leukocytes (Blood Smear) [%]	Day 8	n	1	0	0	1	3
		Mean (SD)	25.0 (-)	- (-)	- (-)	25.0 (-)	40.0 (13.5)
		Min	25	-	-	25	25
		Median	25.0	-	-	25.0	44.0
		Max	25	-	-	25	51
	Day 29	n	0	0	0	0	3
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	57.3 (3.1)
		Min	-	-	-	-	54
		Median	-	-	-	-	58.0
		Max	-	-	-	-	60
	Day 50	n	0	0	0	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	45.5 (-)
		Min	-	-	-	-	43
		Median	-	-	-	-	45.5
		Max	-	-	-	-	48

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Monocytes (Blood) [10^9/L]	Day -30 to 0	n	12	12	12	36	93
		Mean (SD)	0.501 (0.140)	0.453 (0.101)	0.433 (0.132)	0.462 (0.125)	0.446 (0.113)
		Min	0.36	0.30	0.22	0.22	0.22
		Median	0.465	0.450	0.425	0.450	0.440
		Max	0.77	0.62	0.64	0.77	0.77
	Day 1	n	12	12	12	36	94
		Mean (SD)	0.497 (0.099)	0.462 (0.157)	0.460 (0.104)	0.473 (0.120)	0.454 (0.114)
		Min	0.35	0.20	0.26	0.20	0.20
		Median	0.485	0.450	0.440	0.460	0.450
		Max	0.68	0.71	0.62	0.71	0.82
	Day 2	n	12	12	12	36	96
		Mean (SD)	0.543 (0.151)	0.586 (0.171)	0.548 (0.163)	0.559 (0.158)	0.555 (0.154)
		Min	0.36	0.38	0.32	0.32	0.24
		Median	0.505	0.520	0.525	0.520	0.520
		Max	0.80	0.95	0.93	0.95	1.05

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Monocytes (Blood) [10^9/L]	Day 8	n	11	12	12	35	93
		Mean (SD)	0.485 (0.151)	0.458 (0.165)	0.403 (0.107)	0.447 (0.143)	0.428 (0.129)
		Min	0.25	0.30	0.24	0.24	0.16
		Median	0.430	0.405	0.395	0.410	0.400
		Max	0.77	0.90	0.63	0.90	0.90
	Day 29	n	12	12	12	36	90
		Mean (SD)	0.442 (0.127)	0.428 (0.145)	0.380 (0.135)	0.416 (0.135)	0.403 (0.115)
		Min	0.27	0.25	0.17	0.17	0.17
		Median	0.415	0.380	0.355	0.380	0.380
		Max	0.72	0.82	0.58	0.82	0.82
	Day 50	n	10	11	12	33	90
		Mean (SD)	0.520 (0.184)	0.536 (0.141)	0.431 (0.085)	0.493 (0.143)	0.449 (0.145)
		Min	0.26	0.37	0.28	0.26	0.11
		Median	0.525	0.490	0.415	0.490	0.425
		Max	0.86	0.82	0.61	0.86	1.08

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Monocytes (Blood Smear) [10^9/L]	Day -30 to 0	n	0	0	0	0	3
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	0.383 (0.235)
		Min	-	-	-	-	0.18
		Median	-	-	-	-	0.330
		Max	-	-	-	-	0.64
	Day 1	n	0	0	0	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	0.470 (-)
		Min	-	-	-	-	0.29
		Median	-	-	-	-	0.470
		Max	-	-	-	-	0.65
	Day 8	n	1	0	0	1	3
		Mean (SD)	0.290 (-)	- (-)	- (-)	0.290 (-)	0.357 (0.091)
		Min	0.29	-	-	0.29	0.29
		Median	0.290	-	-	0.290	0.320
		Max	0.29	-	-	0.29	0.46

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Monocytes (Blood Smear) [10^9/L]	Day 29	n	0	0	0	0	3
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	0.440 (0.115)
		Min	-	-	-	-	0.35
		Median	-	-	-	-	0.400
		Max	-	-	-	-	0.57
	Day 50	n	0	0	0	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	0.345 (-)
		Min	-	-	-	-	0.32
		Median	-	-	-	-	0.345
		Max	-	-	-	-	0.37
Monocytes/Leukocytes (Blood) [%]	Day -30 to 0	n	12	12	12	36	93
		Mean (SD)	8.61 (1.33)	7.77 (0.97)	8.05 (2.44)	8.14 (1.69)	8.20 (1.84)
		Min	6.7	5.7	4.3	4.3	4.1
		Median	8.55	7.80	7.90	7.95	8.00
		Max	10.9	9.6	13.1	13.1	13.1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Monocytes/Leukocytes (Blood) [%]	Day 1	n	12	12	12	36	94
		Mean (SD)	8.78 (1.34)	8.63 (2.24)	8.03 (1.87)	8.48 (1.83)	8.57 (1.77)
		Min	7.0	5.8	5.4	5.4	4.4
		Median	8.80	8.05	8.10	8.25	8.40
		Max	10.9	12.7	10.9	12.7	13.1
	Day 2	n	12	12	12	36	96
		Mean (SD)	9.55 (1.67)	9.63 (1.45)	9.56 (1.93)	9.58 (1.64)	9.66 (1.94)
		Min	6.6	7.2	6.9	6.6	4.4
		Median	9.30	9.90	9.45	9.50	9.55
		Max	12.9	12.1	13.3	13.3	14.5
	Day 8	n	11	12	12	35	93
		Mean (SD)	9.10 (1.96)	8.10 (1.46)	7.51 (1.55)	8.21 (1.74)	8.30 (1.88)
		Min	6.4	6.3	5.9	5.9	3.9
		Median	9.70	8.20	7.05	8.20	8.20
		Max	12.5	10.5	10.7	12.5	14.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Monocytes/Leukocytes (Blood) [%]	Day 29	n	12	12	12	36	90
		Mean (SD)	8.24 (1.92)	7.94 (1.68)	7.43 (2.33)	7.87 (1.97)	8.01 (1.91)
		Min	5.9	5.8	3.8	3.8	3.8
		Median	8.30	7.75	7.20	7.75	7.95
		Max	12.8	10.8	10.7	12.8	12.8
	Day 50	n	10	11	12	33	90
		Mean (SD)	9.26 (2.32)	9.22 (1.40)	8.63 (1.39)	9.02 (1.70)	8.69 (2.05)
		Min	5.2	6.8	6.4	5.2	2.8
		Median	10.00	9.50	8.55	8.90	8.70
		Max	12.5	11.0	11.0	12.5	14.0
Monocytes/Leukocytes (Blood Smear) [%]	Day -30 to 0	n	0	0	0	0	3
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	6.3 (3.5)
		Min	-	-	-	-	3
		Median	-	-	-	-	6.0
		Max	-	-	-	-	10

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Monocytes/Leukocytes (Blood Smear) [%]	Day 1	n	0	0	0	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	9.5 (-)
		Min	-	-	-	-	6
		Median	-	-	-	-	9.5
		Max	-	-	-	-	13
	Day 8	n	1	0	0	1	3
		Mean (SD)	6.0 (-)	- (-)	- (-)	6.0 (-)	6.7 (1.2)
		Min	6	-	-	6	6
		Median	6.0	-	-	6.0	6.0
		Max	6	-	-	6	8
	Day 29	n	0	0	0	0	3
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	7.3 (3.2)
		Min	-	-	-	-	5
		Median	-	-	-	-	6.0
		Max	-	-	-	-	11

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Monocytes/Leukocytes (Blood Smear) [%]	Day 50	n	0	0	0	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	6.5 (-)
		Min	-	-	-	-	6
		Median	-	-	-	-	6.5
		Max	-	-	-	-	7
Neutrophils (Blood) [10^9/L]	Day -30 to 0	n	12	12	12	36	93
		Mean (SD)	3.506 (1.024)	3.293 (0.797)	3.385 (1.050)	3.395 (0.940)	3.133 (0.874)
		Min	1.51	1.72	1.92	1.51	1.51
		Median	3.585	3.220	3.265	3.335	3.080
		Max	5.42	4.55	6.07	6.07	6.07
	Day 1	n	12	12	12	36	94
		Mean (SD)	3.519 (0.881)	2.965 (0.796)	3.713 (1.240)	3.399 (1.015)	3.122 (1.012)
		Min	2.02	1.86	2.32	1.86	1.35
		Median	3.395	3.095	3.280	3.170	2.965
		Max	5.08	4.32	6.55	6.55	6.55

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Neutrophils (Blood) [10^9/L]	Day 2	n	12	12	12	36	96
		Mean (SD)	3.549 (0.848)	3.774 (1.178)	4.048 (1.030)	3.790 (1.019)	3.644 (1.065)
		Min	2.16	2.56	2.51	2.16	1.79
		Median	3.600	3.330	4.405	3.570	3.410
		Max	5.34	6.55	5.61	6.55	6.89
	Day 8	n	11	12	12	35	93
		Mean (SD)	3.034 (0.984)	3.103 (1.081)	3.234 (1.472)	3.126 (1.171)	2.896 (1.109)
		Min	1.51	1.64	1.56	1.51	1.17
		Median	3.300	3.010	2.940	2.990	2.710
		Max	4.60	5.72	6.27	6.27	6.27
	Day 29	n	12	12	12	36	90
		Mean (SD)	3.117 (0.762)	2.963 (0.802)	2.866 (0.915)	2.982 (0.812)	2.792 (0.882)
		Min	1.54	1.87	1.72	1.54	1.44
		Median	2.990	2.785	2.645	2.900	2.650
		Max	4.59	4.32	5.23	5.23	6.64

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Neutrophils (Blood) [10^9/L]	Day 50	n	10	11	12	33	90
		Mean (SD)	3.152 (1.148)	3.207 (0.872)	2.849 (0.813)	3.060 (0.928)	2.888 (0.954)
		Min	1.16	1.85	1.60	1.16	1.16
		Median	3.315	3.300	2.890	3.040	2.860
		Max	4.80	4.44	4.18	4.80	6.05
Neutrophils (Blood Smear) [10^9/L]	Day -30 to 0	n	0	0	0	0	3
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.30 (1.30)
		Min	-	-	-	-	0.5
		Median	-	-	-	-	0.60
		Max	-	-	-	-	2.8
	Day 1	n	0	0	0	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.65 (-)
		Min	-	-	-	-	1.4
		Median	-	-	-	-	1.65
		Max	-	-	-	-	1.9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Neutrophils (Blood Smear) [10^9/L]	Day 8	n	1	0	0	1	3
		Mean (SD)	3.10 (-)	- (-)	- (-)	3.10 (-)	2.03 (1.01)
		Min	3.1	-	-	3.1	1.1
		Median	3.10	-	-	3.10	1.90
		Max	3.1	-	-	3.1	3.1
	Day 29	n	0	0	0	0	3
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.87 (0.55)
		Min	-	-	-	-	1.3
		Median	-	-	-	-	1.90
		Max	-	-	-	-	2.4
	Day 50	n	0	0	0	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	1.90 (-)
		Min	-	-	-	-	1.9
		Median	-	-	-	-	1.90
		Max	-	-	-	-	1.9

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Neutrophils/Leukocytes (Blood) [%]	Day -30 to 0	n	12	12	12	36	93
		Mean (SD)	59.49 (7.83)	56.27 (8.93)	60.98 (7.46)	58.91 (8.11)	56.41 (7.33)
		Min	44.3	41.0	51.9	41.0	41.0
		Median	60.60	56.10	59.80	59.45	56.10
		Max	69.6	67.7	76.8	76.8	76.8
	Day 1	n	12	12	12	36	94
		Mean (SD)	61.36 (7.96)	55.98 (10.47)	62.57 (8.61)	59.97 (9.28)	57.38 (8.46)
		Min	48.1	39.8	50.0	39.8	39.8
		Median	62.05	56.80	59.75	59.00	57.05
		Max	73.7	77.5	80.9	80.9	80.9
	Day 2	n	12	12	12	36	96
		Mean (SD)	62.43 (7.02)	61.76 (8.07)	70.04 (5.68)	64.74 (7.79)	62.54 (8.22)
		Min	47.5	45.4	61.9	45.4	41.1
		Median	63.75	64.15	70.00	65.10	63.35
		Max	70.7	72.5	79.0	79.0	79.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Neutrophils/Leukocytes (Blood) [%]	Day 8	n	11	12	12	35	93
		Mean (SD)	56.26 (9.34)	54.31 (7.84)	56.94 (11.70)	55.83 (9.55)	54.15 (8.51)
		Min	36.7	40.5	43.4	36.7	36.7
		Median	59.50	57.25	57.20	58.50	54.80
		Max	67.1	63.2	81.4	81.4	81.4
	Day 29	n	12	12	12	36	90
		Mean (SD)	57.61 (7.75)	54.95 (6.73)	54.97 (9.09)	55.84 (7.79)	54.12 (8.10)
		Min	41.7	44.5	39.9	39.9	37.5
		Median	57.70	55.80	55.35	55.80	54.00
		Max	68.9	65.3	75.8	75.8	75.8
	Day 50	n	10	11	12	33	90
		Mean (SD)	54.80 (10.88)	54.17 (6.56)	55.92 (9.36)	55.00 (8.80)	54.63 (8.09)
		Min	36.1	43.1	43.2	36.1	36.1
		Median	55.50	56.20	58.40	56.70	54.60
		Max	68.1	67.3	74.6	74.6	74.6

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Neutrophils/Leukocytes (Blood Smear) [%]	Day -30 to 0	n	0	0	0	0	3
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	22.7 (24.5)
		Min	-	-	-	-	8
		Median	-	-	-	-	9.0
		Max	-	-	-	-	51
	Day 1	n	0	0	0	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	33.0 (-)
		Min	-	-	-	-	28
		Median	-	-	-	-	33.0
		Max	-	-	-	-	38
	Day 8	n	1	0	0	1	3
		Mean (SD)	63.0 (-)	- (-)	- (-)	63.0 (-)	39.0 (21.9)
		Min	63	-	-	63	20
		Median	63.0	-	-	63.0	34.0
		Max	63	-	-	63	63

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Neutrophils/Leukocytes (Blood Smear) [%]	Day 29	n	0	0	0	0	3
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	29.7 (5.7)
		Min	-	-	-	-	25
		Median	-	-	-	-	28.0
		Max	-	-	-	-	36
	Day 50	n	0	0	0	0	2
		Mean (SD)	- (-)	- (-)	- (-)	- (-)	35.5 (-)
		Min	-	-	-	-	35
		Median	-	-	-	-	35.5
		Max	-	-	-	-	36
Platelets [10^9/L]	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	240.8 (39.4)	222.1 (51.4)	256.0 (34.3)	239.6 (43.4)	238.6 (45.9)
		Min	155	120	175	120	120
		Median	239.5	240.5	254.0	247.5	240.0
		Max	303	304	318	318	361

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Platelets [10^9/L]	Day 1	n	12	12	12	36	96
		Mean (SD)	215.8 (64.3)	231.5 (47.5)	264.4 (38.0)	237.3 (53.7)	229.6 (47.8)
		Min	66	143	180	66	66
		Median	225.5	235.5	267.0	249.5	233.0
		Max	301	305	342	342	342
	Day 2	n	12	12	12	36	96
		Mean (SD)	216.6 (42.4)	226.4 (43.9)	237.3 (35.2)	226.8 (40.4)	223.5 (41.4)
		Min	158	152	156	152	140
		Median	208.0	231.0	241.5	231.0	221.5
		Max	277	304	301	304	309
	Day 8	n	12	12	12	36	96
		Mean (SD)	233.9 (33.5)	240.8 (40.9)	268.5 (35.0)	247.7 (38.6)	239.7 (44.0)
		Min	161	171	189	161	160
		Median	233.0	236.5	267.5	245.0	241.5
		Max	295	308	334	334	346

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.1-3: Laboratory: Descriptive statistics, continuous (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Platelets [10^9/L]	Day 29	n	12	12	12	36	94
		Mean (SD)	228.6 (39.3)	247.3 (40.4)	265.9 (40.2)	247.3 (41.8)	235.8 (46.7)
		Min	154	170	174	154	143
		Median	233.5	254.5	267.0	252.0	238.0
		Max	283	297	339	339	349
	Day 50	n	10	11	12	33	92
		Mean (SD)	229.4 (41.2)	257.3 (71.3)	263.8 (35.6)	251.2 (52.2)	234.2 (48.8)
		Min	156	163	195	156	155
		Median	231.5	246.0	262.5	251.0	228.0
		Max	304	397	308	397	397

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Alanine Aminotransferase [U/L]	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	21.75 (9.82)	19.58 (7.01)	20.92 (11.64)	18.08 (7.14)	24.00 (12.43)	20.87 (9.74)
		Min	7.0	12.0	10.0	10.0	12.0	7.0
		Median	21.00	19.00	18.00	15.50	19.00	18.00
		Max	37.0	36.0	48.0	34.0	47.0	48.0
	Day 1	n	12	12	12	12	12	60
		Mean (SD)	19.75 (10.07)	18.75 (6.25)	17.25 (13.59)	17.75 (7.96)	21.42 (12.30)	18.98 (10.15)
		Min	5.0	10.0	8.0	10.0	11.0	5.0
		Median	17.00	17.50	13.00	17.50	16.00	17.00
		Max	38.0	31.0	58.0	33.0	45.0	58.0
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	21.08 (10.26)	18.67 (6.07)	16.58 (10.99)	17.58 (7.03)	20.75 (11.68)	18.93 (9.32)
		Min	6.0	11.0	8.0	9.0	11.0	6.0
		Median	18.50	17.50	12.50	17.50	16.50	17.00
		Max	41.0	32.0	48.0	30.0	45.0	48.0

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Alanine Aminotransferase [U/L]	Day 8	n	12	12	12	12	12	60
		Mean (SD)	19.92 (8.88)	19.75 (10.15)	18.08 (11.28)	16.67 (5.09)	22.25 (10.40)	19.33 (9.29)
		Min	9.0	9.0	8.0	10.0	12.0	8.0
		Median	19.50	16.00	16.00	15.50	20.00	17.00
		Max	40.0	39.0	49.0	24.0	39.0	49.0
	Day 29	n	12	12	12	12	12	60
		Mean (SD)	19.17 (8.36)	17.83 (8.20)	18.17 (11.78)	21.17 (12.35)	26.83 (17.71)	20.63 (12.23)
		Min	8.0	9.0	9.0	9.0	10.0	8.0
		Median	17.00	16.00	14.00	18.00	20.50	17.00
		Max	40.0	37.0	46.0	53.0	65.0	65.0
	Day 50	n	11	12	12	12	12	59
		Mean (SD)	20.09 (8.93)	21.17 (11.71)	18.08 (13.22)	17.83 (6.52)	22.42 (15.41)	19.92 (11.37)
		Min	8.0	11.0	8.0	11.0	11.0	8.0
		Median	17.00	17.50	13.00	15.50	18.50	17.00
		Max	34.0	51.0	53.0	28.0	68.0	68.0

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Albumin [g/L]	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	44.9 (2.2)	44.3 (2.0)	45.2 (2.6)	44.9 (2.2)	45.0 (2.1)	44.9 (2.2)
		Min	41	42	41	41	40	40
		Median	45.0	44.5	45.5	44.5	45.5	45.0
		Max	49	48	49	49	48	49
	Day 1	n	12	12	12	12	12	60
		Mean (SD)	43.6 (2.9)	40.8 (2.5)	42.9 (2.5)	42.5 (1.8)	41.3 (1.5)	42.2 (2.4)
		Min	40	37	37	39	40	37
		Median	43.0	40.5	43.5	43.0	41.0	42.0
		Max	49	44	46	45	45	49
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	43.7 (2.0)	41.3 (1.7)	41.9 (2.0)	42.3 (2.3)	42.7 (3.2)	42.4 (2.4)
		Min	41	39	38	38	38	38
		Median	43.5	41.0	42.0	42.0	42.5	42.0
		Max	47	44	45	46	47	47

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Albumin [g/L]	Day 8	n	12	12	12	12	12	60
		Mean (SD)	42.3 (2.1)	42.0 (2.7)	43.1 (1.7)	43.5 (2.7)	42.3 (2.3)	42.6 (2.3)
		Min	39	39	39	41	39	39
		Median	42.0	41.5	43.0	43.0	42.0	42.0
		Max	45	48	45	50	45	50
	Day 29	n	12	12	12	12	12	60
		Mean (SD)	42.6 (2.2)	41.3 (2.1)	42.0 (1.8)	41.7 (2.6)	40.8 (1.2)	41.7 (2.0)
		Min	39	37	39	37	39	37
		Median	43.0	41.0	42.0	41.0	41.0	41.5
		Max	45	45	45	46	42	46
	Day 50	n	11	12	12	12	12	59
		Mean (SD)	43.0 (3.0)	41.3 (1.8)	41.7 (1.9)	42.9 (2.0)	43.0 (1.5)	42.4 (2.2)
		Min	39	39	39	38	40	38
		Median	43.0	40.5	42.0	43.0	43.0	43.0
		Max	48	45	45	46	45	48

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Alkaline Phosphatase [U/L]	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	57.9 (9.9)	63.1 (19.9)	55.4 (11.1)	53.6 (13.5)	65.3 (17.0)	59.1 (14.9)
		Min	46	38	38	37	43	37
		Median	54.0	60.5	54.5	48.5	62.5	55.0
		Max	74	112	80	78	99	112
	Day 1	n	12	12	12	12	12	60
		Mean (SD)	54.2 (8.9)	57.8 (17.6)	56.3 (12.2)	51.8 (13.4)	60.9 (15.1)	56.2 (13.7)
		Min	41	34	41	36	44	34
		Median	54.5	56.0	53.0	48.0	58.5	54.0
		Max	68	101	87	81	89	101
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	55.4 (9.0)	59.1 (19.9)	56.4 (13.0)	53.1 (14.5)	64.8 (16.0)	57.8 (15.0)
		Min	43	37	40	37	44	37
		Median	54.5	56.5	53.0	49.5	64.5	54.0
		Max	68	110	88	82	89	110

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Alkaline Phosphatase [U/L]	Day 8	n	12	12	12	12	12	60
		Mean (SD)	55.8 (10.6)	59.3 (18.8)	56.8 (12.0)	54.0 (14.8)	65.8 (19.0)	58.4 (15.5)
		Min	46	38	41	36	44	36
		Median	53.0	53.5	55.0	49.5	59.5	55.0
		Max	82	97	85	82	108	108
	Day 29	n	12	12	12	12	12	60
		Mean (SD)	57.2 (7.6)	57.8 (20.3)	57.3 (12.6)	53.7 (16.2)	66.7 (24.0)	58.5 (17.1)
		Min	48	35	42	34	45	34
		Median	54.0	53.0	54.0	50.0	60.5	54.0
		Max	70	108	83	86	132	132
	Day 50	n	11	12	12	12	12	59
		Mean (SD)	56.2 (9.0)	57.6 (17.6)	57.4 (12.2)	51.7 (14.7)	64.3 (18.0)	57.4 (14.9)
		Min	42	34	40	37	39	34
		Median	52.0	53.0	54.0	46.5	62.5	53.0
		Max	69	96	77	86	95	96

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Amylase [U/L]	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	58.7 (20.7)	56.8 (24.4)	52.0 (16.6)	66.1 (28.8)	51.0 (16.7)	56.9 (21.9)
		Min	20	33	30	37	29	20
		Median	57.0	50.0	50.0	57.0	48.5	51.0
		Max	91	120	79	131	81	131
	Day 1	n	12	12	12	12	12	60
		Mean (SD)	58.8 (22.7)	51.9 (21.5)	48.3 (13.9)	62.6 (25.5)	51.3 (16.8)	54.6 (20.5)
		Min	20	28	30	34	26	20
		Median	54.5	45.5	47.0	51.5	53.0	50.0
		Max	98	102	78	108	74	108
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	61.0 (25.0)	54.2 (19.2)	48.4 (15.3)	60.1 (21.1)	47.4 (14.7)	54.2 (19.6)
		Min	19	34	28	34	26	19
		Median	54.0	51.0	46.5	54.5	47.0	49.5
		Max	113	102	79	94	74	113

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Amylase [U/L]	Day 8	n	12	12	12	12	12	60
		Mean (SD)	55.8 (21.4)	52.7 (22.8)	50.9 (17.3)	63.0 (27.6)	53.2 (20.8)	55.1 (21.9)
		Min	17	34	29	36	24	17
		Median	54.0	43.5	45.0	48.5	56.5	50.5
		Max	83	112	88	123	96	123
	Day 29	n	12	12	12	12	12	60
		Mean (SD)	58.9 (19.5)	52.9 (18.4)	50.9 (16.8)	60.4 (22.0)	53.1 (22.0)	55.3 (19.5)
		Min	20	33	28	39	27	20
		Median	56.0	50.5	50.5	49.0	47.5	50.5
		Max	88	93	80	103	105	105
	Day 50	n	11	12	12	12	12	59
		Mean (SD)	56.5 (19.5)	49.5 (17.3)	53.3 (18.6)	59.1 (24.0)	47.8 (17.4)	53.2 (19.3)
		Min	19	29	26	23	23	19
		Median	54.0	45.0	52.5	51.5	48.5	52.0
		Max	84	93	80	105	80	105

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Aspartate Aminotransferase [U/L]	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	20.8 (3.5)	20.3 (4.3)	18.2 (4.5)	20.2 (3.7)	22.0 (7.5)	20.3 (4.9)
		Min	16	14	11	15	15	11
		Median	21.0	20.5	18.0	20.0	20.0	20.0
		Max	27	28	29	27	42	42
	Day 1	n	12	12	12	12	12	60
		Mean (SD)	23.2 (12.8)	19.6 (5.1)	17.7 (4.0)	20.6 (5.4)	21.9 (12.5)	20.6 (8.7)
		Min	14	12	11	14	15	11
		Median	20.0	18.5	17.0	18.5	18.0	18.5
		Max	62	31	24	32	60	62
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	22.8 (7.4)	17.3 (3.4)	19.3 (9.6)	18.1 (3.4)	20.6 (7.9)	19.6 (6.8)
		Min	15	11	12	14	15	11
		Median	21.5	17.0	17.0	18.0	18.0	18.0
		Max	43	23	49	26	43	49

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Aspartate Aminotransferase [U/L]	Day 8	n	12	12	12	12	12	60
		Mean (SD)	19.2 (3.8)	23.7 (10.9)	17.7 (4.4)	19.3 (3.3)	21.9 (8.8)	20.3 (7.0)
		Min	15	11	11	14	15	11
		Median	17.5	20.0	17.5	19.5	18.5	19.0
		Max	26	47	26	25	46	47
	Day 29	n	12	12	12	12	12	60
		Mean (SD)	22.0 (9.6)	19.8 (6.2)	17.3 (4.6)	19.3 (5.5)	22.5 (10.2)	20.2 (7.6)
		Min	14	13	11	13	13	11
		Median	21.0	19.0	16.0	18.0	19.0	18.0
		Max	51	35	26	32	49	51
	Day 50	n	11	12	12	12	12	59
		Mean (SD)	20.8 (4.2)	20.9 (4.7)	18.2 (4.3)	23.3 (9.4)	20.8 (6.6)	20.8 (6.2)
		Min	12	15	10	15	15	10
		Median	21.0	21.0	17.5	19.0	19.5	20.0
		Max	27	33	27	45	40	45

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Bilirubin (Serum) [µmol/L]	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	10.28 (5.19)	8.03 (4.03)	8.02 (3.35)	9.54 (4.53)	8.53 (5.43)	8.88 (4.50)
		Min	2.7	3.2	1.3	3.8	3.8	1.3
		Median	9.40	5.90	8.75	8.30	5.90	8.30
		Max	20.9	16.9	13.2	19.3	21.2	21.2
	Day 1	n	12	12	12	12	12	60
		Mean (SD)	9.31 (6.57)	6.91 (5.27)	8.07 (3.49)	7.93 (3.88)	8.02 (5.77)	8.05 (5.01)
		Min	3.2	2.7	4.4	4.4	3.2	2.7
		Median	7.85	4.55	6.55	6.05	6.05	6.30
		Max	27.9	19.8	15.4	15.6	23.8	27.9
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	8.18 (3.36)	7.03 (5.23)	10.90 (4.76)	10.50 (6.66)	12.43 (9.43)	9.81 (6.33)
		Min	3.2	1.3	5.1	3.9	1.3	1.3
		Median	7.25	5.20	10.80	8.15	11.15	8.20
		Max	14.0	18.3	18.0	23.3	40.0	40.0

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Bilirubin (Serum) [µmol/L]	Day 8	n	12	12	12	12	12	60
		Mean (SD)	9.53 (5.09)	7.06 (4.84)	6.95 (4.11)	6.73 (4.52)	6.58 (3.57)	7.37 (4.44)
		Min	3.1	3.8	1.3	1.3	2.9	1.3
		Median	7.95	4.90	5.80	5.95	4.80	5.90
		Max	22.1	18.5	13.3	16.1	13.3	22.1
	Day 29	n	12	12	12	12	12	60
		Mean (SD)	8.95 (5.15)	6.72 (3.89)	7.39 (3.75)	6.63 (3.58)	6.81 (4.15)	7.30 (4.09)
		Min	1.3	1.3	3.1	1.3	2.9	1.3
		Median	8.90	5.55	6.40	6.00	5.15	6.15
		Max	20.3	14.2	14.4	13.2	14.5	20.3
	Day 50	n	11	12	12	12	12	59
		Mean (SD)	9.76 (5.56)	7.00 (3.34)	8.23 (3.69)	7.23 (3.48)	8.59 (5.94)	8.13 (4.47)
		Min	3.1	3.2	2.7	1.3	1.3	1.3
		Median	8.40	6.15	7.60	7.10	7.95	7.50
		Max	20.3	13.3	14.0	13.2	18.3	20.3

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
C Reactive Protein [mg/L]	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	0.833 (0.993)	1.629 (2.534)	0.550 (0.509)	0.654 (0.436)	0.733 (0.657)	0.880 (1.303)
		Min	0.15	0.15	0.15	0.15	0.15	0.15
		Median	0.325	0.400	0.275	0.650	0.600	0.500
		Max	3.50	8.70	1.50	1.30	2.30	8.70
	Day 1	n	12	12	12	12	12	60
		Mean (SD)	0.638 (0.640)	1.538 (2.189)	1.200 (1.199)	0.496 (0.250)	0.929 (0.904)	0.960 (1.244)
		Min	0.15	0.15	0.15	0.15	0.15	0.15
		Median	0.350	0.550	0.900	0.550	0.650	0.550
		Max	2.00	7.40	3.70	0.90	3.30	7.40
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	0.638 (0.614)	1.763 (2.279)	1.517 (1.132)	1.496 (1.580)	2.363 (1.342)	1.555 (1.547)
		Min	0.15	0.15	0.40	0.15	0.15	0.15
		Median	0.400	0.550	1.500	0.850	2.050	1.100
		Max	2.00	6.90	4.40	5.70	4.70	6.90

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
C Reactive Protein [mg/L]	Day 8	n	12	12	12	12	12	60
		Mean (SD)	3.283 (8.943)	1.983 (2.648)	1.088 (0.766)	0.629 (0.548)	0.933 (1.015)	1.583 (4.186)
		Min	0.15	0.20	0.15	0.15	0.15	0.15
		Median	0.550	0.750	0.900	0.450	0.650	0.600
		Max	31.60	7.70	2.50	2.00	3.90	31.60
	Day 29	n	12	12	12	12	12	60
		Mean (SD)	0.938 (0.984)	1.350 (1.388)	1.363 (1.641)	1.213 (0.940)	1.238 (1.192)	1.220 (1.223)
		Min	0.15	0.40	0.15	0.15	0.15	0.15
		Median	0.550	0.700	0.600	1.100	0.700	0.700
		Max	3.10	5.00	5.20	3.10	3.90	5.20
	Day 50	n	11	12	12	12	12	59
		Mean (SD)	0.964 (0.709)	2.067 (2.309)	0.779 (0.638)	1.008 (0.832)	1.483 (2.013)	1.265 (1.516)
		Min	0.10	0.20	0.15	0.30	0.20	0.10
		Median	0.900	0.750	0.600	0.800	0.750	0.700
		Max	2.00	6.70	2.40	2.80	7.50	7.50

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Calcium [mmol/L]	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	2.341 (0.072)	2.364 (0.068)	2.358 (0.093)	2.363 (0.086)	2.366 (0.075)	2.358 (0.077)
		Min	2.18	2.21	2.25	2.26	2.19	2.18
		Median	2.355	2.355	2.335	2.345	2.390	2.360
		Max	2.42	2.48	2.50	2.57	2.46	2.57
	Day 1	n	12	12	12	12	12	60
		Mean (SD)	2.274 (0.089)	2.283 (0.086)	2.323 (0.062)	2.307 (0.087)	2.292 (0.090)	2.296 (0.083)
		Min	2.11	2.14	2.23	2.15	2.13	2.11
		Median	2.275	2.300	2.320	2.305	2.295	2.300
		Max	2.43	2.39	2.42	2.48	2.41	2.48
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	2.308 (0.047)	2.302 (0.060)	2.315 (0.043)	2.308 (0.069)	2.297 (0.094)	2.306 (0.063)
		Min	2.22	2.19	2.25	2.21	2.21	2.19
		Median	2.305	2.300	2.305	2.295	2.245	2.300
		Max	2.39	2.40	2.40	2.46	2.48	2.48

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Calcium [mmol/L]	Day 8	n	12	12	12	12	12	60
		Mean (SD)	2.284 (0.069)	2.313 (0.074)	2.329 (0.044)	2.313 (0.083)	2.286 (0.082)	2.305 (0.072)
		Min	2.16	2.17	2.27	2.19	2.12	2.12
		Median	2.285	2.325	2.330	2.310	2.280	2.315
		Max	2.39	2.45	2.42	2.49	2.42	2.49
	Day 29	n	12	12	12	12	12	60
		Mean (SD)	2.299 (0.088)	2.323 (0.071)	2.306 (0.068)	2.288 (0.109)	2.248 (0.076)	2.293 (0.085)
		Min	2.14	2.16	2.21	2.13	2.08	2.08
		Median	2.280	2.320	2.290	2.270	2.255	2.290
		Max	2.47	2.43	2.40	2.53	2.32	2.53
	Day 50	n	11	12	12	12	12	59
		Mean (SD)	2.304 (0.094)	2.314 (0.081)	2.320 (0.078)	2.313 (0.089)	2.303 (0.078)	2.311 (0.081)
		Min	2.12	2.20	2.20	2.19	2.17	2.12
		Median	2.290	2.315	2.300	2.300	2.315	2.310
		Max	2.45	2.44	2.43	2.52	2.41	2.52

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Creatinine [µmol/L]	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	79.04 (14.53)	75.30 (10.58)	78.31 (14.89)	71.23 (13.53)	88.83 (14.78)	78.54 (14.53)
		Min	61.9	61.0	56.6	53.0	65.4	53.0
		Median	77.80	73.85	78.70	67.15	91.50	77.35
		Max	102.5	91.9	102.5	95.5	110.5	110.5
	Day 1	n	12	12	12	12	12	60
		Mean (SD)	79.27 (12.23)	75.51 (12.12)	74.86 (14.26)	69.09 (9.99)	80.52 (12.94)	75.85 (12.62)
		Min	61.9	59.2	55.7	53.0	60.1	53.0
		Median	77.80	74.70	75.15	69.85	85.70	75.10
		Max	98.1	103.4	96.4	88.4	94.6	103.4
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	80.51 (12.07)	75.36 (11.34)	76.38 (13.61)	71.60 (11.08)	85.15 (15.00)	77.80 (13.13)
		Min	63.6	55.7	58.3	51.3	59.2	51.3
		Median	80.90	77.35	75.55	74.25	90.20	76.00
		Max	98.1	93.7	99.0	90.2	104.3	104.3

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Creatinine [µmol/L]	Day 8	n	12	12	12	12	12	60
		Mean (SD)	78.83 (13.02)	70.41 (11.88)	76.62 (13.62)	72.12 (13.69)	77.79 (13.57)	75.15 (13.15)
		Min	61.9	53.9	60.1	45.1	57.5	45.1
		Median	81.30	72.05	74.30	71.60	78.70	74.30
		Max	101.7	86.6	100.8	91.1	95.5	101.7
	Day 29	n	12	12	12	12	12	60
		Mean (SD)	78.18 (13.82)	72.13 (10.47)	75.36 (14.30)	72.27 (15.71)	76.84 (15.10)	74.96 (13.74)
		Min	57.5	56.6	58.3	48.6	52.2	48.6
		Median	77.80	72.95	70.30	71.20	80.45	73.85
		Max	101.7	87.5	101.7	103.4	99.0	103.4
	Day 50	n	11	12	12	12	12	59
		Mean (SD)	78.59 (10.98)	71.53 (9.03)	73.44 (15.72)	74.93 (13.52)	78.22 (13.11)	75.28 (12.57)
		Min	63.6	57.5	54.8	52.2	54.8	52.2
		Median	78.70	70.70	68.95	70.70	78.20	72.50
		Max	99.0	88.4	107.8	99.9	95.5	107.8

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Ferritin [µg/L]	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	70.40 (75.68)	73.14 (66.44)	50.12 (51.25)	69.08 (44.02)	75.84 (51.77)	67.72 (57.67)
		Min	17.4	8.2	6.4	21.6	14.2	6.4
		Median	41.65	53.10	39.00	64.65	51.60	47.70
		Max	256.4	221.4	195.2	141.5	184.7	256.4
	Day 1	n	12	12	12	12	12	60
		Mean (SD)	64.57 (67.18)	66.08 (59.53)	49.32 (41.79)	59.48 (36.90)	63.61 (32.54)	60.61 (48.13)
		Min	11.7	8.4	8.8	19.4	19.3	8.4
		Median	40.60	44.70	36.85	47.35	59.70	46.05
		Max	203.6	216.2	152.2	137.6	117.8	216.2
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	63.65 (66.43)	68.84 (64.34)	51.63 (42.17)	65.85 (40.39)	71.64 (33.70)	64.32 (49.91)
		Min	13.0	7.3	10.9	21.1	20.7	7.3
		Median	38.45	55.95	44.15	55.35	66.75	52.40
		Max	202.3	233.3	155.6	155.4	122.8	233.3

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Ferritin [µg/L]	Day 8	n	12	12	12	12	12	60
		Mean (SD)	58.05 (65.58)	62.97 (53.95)	46.52 (42.82)	63.61 (42.67)	71.52 (41.81)	60.53 (49.20)
		Min	9.7	7.0	10.9	16.9	16.6	7.0
		Median	30.25	43.10	37.85	53.75	69.05	43.10
		Max	218.4	196.9	157.2	148.4	155.5	218.4
	Day 29	n	12	12	12	12	12	60
		Mean (SD)	55.53 (54.24)	47.42 (35.61)	43.76 (40.10)	61.42 (45.06)	62.60 (32.77)	54.15 (41.48)
		Min	12.3	6.6	6.0	18.5	18.1	6.0
		Median	33.10	39.00	37.30	51.20	57.80	43.80
		Max	167.5	130.2	154.4	144.3	119.4	167.5
	Day 50	n	11	12	12	12	12	59
		Mean (SD)	53.66 (56.74)	41.70 (32.19)	33.08 (35.70)	42.21 (29.86)	45.72 (29.83)	43.10 (37.08)
		Min	10.7	5.7	7.1	9.9	11.9	5.7
		Median	28.80	34.85	20.40	31.95	37.75	31.00
		Max	187.0	122.2	135.2	104.9	123.7	187.0

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Follicle Stimulating Hormone [IU/L]	Day -30 to 0	n	5	7	7	10	4	33
		Mean (SD)	16.10 (24.52)	33.73 (44.27)	4.49 (1.66)	21.17 (25.51)	62.23 (72.75)	24.50 (37.70)
		Min	3.9	3.0	2.3	1.9	4.1	1.9
		Median	6.00	7.30	4.00	5.65	41.05	6.30
		Max	59.9	117.0	6.9	71.1	162.7	162.7
Gamma Glutamyl Transferase [U/L]	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	16.3 (7.4)	19.8 (14.3)	15.9 (7.8)	13.8 (5.8)	15.9 (6.0)	16.4 (8.8)
		Min	7	10	8	8	7	7
		Median	16.5	14.0	14.5	12.0	15.5	15.0
		Max	30	58	34	26	29	58
	Day 1	n	12	12	12	12	12	60
		Mean (SD)	15.4 (7.4)	17.8 (12.3)	14.7 (8.1)	12.0 (5.1)	14.8 (5.7)	14.9 (8.1)
		Min	6	9	8	6	7	6
		Median	15.5	12.0	12.5	10.5	14.0	13.0
		Max	29	50	34	24	26	50

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Gamma Glutamyl Transferase [U/L]	Day 2	n	12	12	12	12	12	60
		Mean (SD)	15.3 (7.3)	17.7 (12.4)	14.3 (8.0)	12.3 (5.0)	15.1 (5.6)	14.9 (8.0)
		Min	6	9	6	7	7	6
		Median	16.0	12.0	12.5	10.5	13.5	13.0
		Max	28	50	33	22	26	50
	Day 8	n	12	12	12	12	12	60
		Mean (SD)	15.7 (7.6)	18.3 (13.6)	14.9 (8.4)	13.0 (4.6)	15.8 (6.4)	15.5 (8.5)
		Min	7	8	7	7	6	6
		Median	15.5	12.5	13.0	12.0	15.0	14.0
		Max	32	54	35	20	29	54
	Day 29	n	12	12	12	12	12	60
		Mean (SD)	14.3 (6.2)	18.2 (14.6)	15.7 (8.5)	15.3 (8.5)	16.9 (6.3)	16.1 (9.1)
		Min	7	8	7	7	10	7
		Median	14.5	12.0	14.0	13.0	14.0	14.0
		Max	26	57	35	35	30	57

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Gamma Glutamyl Transferase [U/L]	Day 50	n	11	12	12	12	12	59
		Mean (SD)	15.9 (8.3)	18.0 (12.7)	16.5 (9.8)	12.4 (5.5)	15.4 (6.4)	15.6 (8.8)
		Min	7	9	6	7	6	6
		Median	15.0	11.5	14.5	11.0	14.0	13.0
		Max	34	47	36	24	29	47
Glucose (Blood) [mmol/L]	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	5.352 (0.513)	5.291 (0.309)	5.231 (0.320)	5.393 (0.490)	5.441 (0.326)	5.342 (0.395)
		Min	4.61	4.73	4.61	4.78	4.84	4.61
		Median	5.255	5.335	5.365	5.310	5.535	5.340
		Max	6.56	5.67	5.62	6.34	5.84	6.56
	Day 1	n	12	12	12	12	12	60
		Mean (SD)	5.354 (0.590)	5.357 (0.403)	5.468 (0.715)	5.343 (0.557)	5.463 (0.381)	5.397 (0.528)
		Min	4.06	4.84	4.84	4.67	4.84	4.06
		Median	5.335	5.310	5.340	5.120	5.530	5.340
		Max	6.39	6.34	7.51	6.28	6.06	7.51

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

Program: Tfsaf_LB_2_1.sas (Page 23 of 66)

Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Glucose (Blood) [mmol/L]	Day 2	n	12	12	12	12	12	60
		Mean (SD)	5.282 (0.368)	5.381 (0.575)	5.393 (0.340)	5.448 (0.695)	5.541 (0.494)	5.409 (0.501)
		Min	4.78	4.84	4.61	4.67	4.95	4.61
		Median	5.170	5.225	5.450	5.255	5.420	5.340
		Max	5.95	7.01	5.84	7.17	6.89	7.17
	Day 8	n	12	12	12	12	12	60
		Mean (SD)	5.537 (0.911)	5.027 (0.390)	5.228 (0.359)	5.365 (0.624)	5.466 (0.517)	5.324 (0.603)
		Min	4.84	4.45	4.56	4.50	4.23	4.23
		Median	5.310	5.030	5.255	5.365	5.530	5.340
		Max	8.28	5.84	5.78	6.39	6.06	8.28
	Day 29	n	12	12	12	12	12	60
		Mean (SD)	5.298 (0.407)	5.230 (0.319)	5.045 (0.450)	5.417 (0.572)	5.441 (0.345)	5.286 (0.438)
		Min	4.67	4.89	4.39	4.56	4.73	4.39
		Median	5.230	5.145	4.920	5.340	5.475	5.230
		Max	6.12	6.00	5.84	6.62	5.95	6.62

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Glucose (Blood) [mmol/L]	Day 50	n	11	12	12	12	12	59
		Mean (SD)	5.256 (0.496)	5.282 (0.362)	5.179 (0.229)	5.370 (0.638)	5.358 (0.287)	5.289 (0.418)
		Min	4.61	4.56	4.78	4.50	4.73	4.50
		Median	5.120	5.310	5.255	5.230	5.395	5.280
		Max	6.23	5.89	5.56	6.84	5.84	6.84
Lipase [U/L]	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	33.6 (11.2)	38.5 (30.3)	31.8 (14.5)	37.9 (15.9)	27.8 (7.1)	33.9 (17.5)
		Min	19	19	16	15	19	15
		Median	29.5	29.0	29.5	35.0	25.0	29.0
		Max	49	133	71	75	40	133
	Day 1	n	12	12	12	12	12	60
		Mean (SD)	34.6 (10.8)	34.9 (14.8)	29.3 (16.4)	39.5 (14.7)	35.0 (16.8)	34.7 (14.7)
		Min	20	21	14	17	19	14
		Median	33.0	31.0	25.0	36.5	34.0	32.0
		Max	49	73	73	72	78	78

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Lipase [U/L]	Day 2	n	12	12	12	12	12	60
		Mean (SD)	39.1 (19.6)	37.1 (17.4)	28.3 (15.3)	32.6 (9.6)	26.4 (9.0)	32.7 (15.1)
		Min	19	19	12	17	15	12
		Median	28.5	34.0	26.5	33.0	25.5	28.5
		Max	81	72	68	46	43	81
	Day 8	n	12	12	12	12	12	60
		Mean (SD)	35.1 (13.2)	35.8 (15.7)	29.9 (14.0)	35.6 (13.2)	43.6 (37.1)	36.0 (20.6)
		Min	18	22	14	22	17	14
		Median	32.5	33.0	29.5	32.5	30.0	31.5
		Max	61	80	65	61	151	151
	Day 29	n	12	12	12	12	12	60
		Mean (SD)	39.0 (15.8)	37.3 (14.4)	31.5 (13.0)	37.3 (10.6)	41.8 (39.0)	37.4 (20.8)
		Min	21	21	15	21	18	15
		Median	33.0	32.0	32.5	37.5	27.5	32.0
		Max	68	66	61	59	160	160

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Lipase [U/L]	Day 50	n	11	12	12	12	12	59
		Mean (SD)	37.3 (13.2)	34.5 (14.2)	32.5 (13.3)	38.1 (12.0)	29.1 (10.1)	34.2 (12.6)
		Min	23	21	15	15	14	14
		Median	34.0	32.5	35.5	42.0	27.0	33.0
		Max	57	72	58	52	45	72
Potassium [mmol/L]	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	4.34 (0.25)	4.38 (0.25)	4.23 (0.24)	4.48 (0.34)	4.46 (0.19)	4.38 (0.26)
		Min	4.0	4.0	3.9	4.0	4.2	3.9
		Median	4.30	4.35	4.25	4.45	4.45	4.30
		Max	4.8	4.7	4.7	5.4	4.9	5.4
	Day 1	n	12	12	12	12	12	60
		Mean (SD)	4.02 (0.25)	4.23 (0.28)	4.08 (0.20)	4.33 (0.52)	4.23 (0.17)	4.18 (0.32)
		Min	3.5	3.6	3.8	3.9	3.9	3.5
		Median	4.00	4.20	4.05	4.15	4.20	4.10
		Max	4.5	4.7	4.4	5.8	4.5	5.8

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Potassium [mmol/L]	Day 2	n	12	12	12	12	12	60
		Mean (SD)	4.38 (0.32)	4.40 (0.32)	4.20 (0.17)	4.30 (0.29)	4.44 (0.31)	4.35 (0.29)
		Min	3.9	3.7	3.9	3.9	3.8	3.7
		Median	4.35	4.45	4.25	4.30	4.50	4.30
		Max	5.1	4.9	4.4	4.8	4.9	5.1
	Day 8	n	12	12	12	12	12	60
		Mean (SD)	4.23 (0.24)	4.23 (0.28)	4.22 (0.20)	4.35 (0.30)	4.35 (0.14)	4.28 (0.24)
		Min	4.0	3.8	3.8	3.9	4.1	3.8
		Median	4.10	4.20	4.25	4.25	4.35	4.30
		Max	4.8	4.9	4.5	4.9	4.6	4.9
	Day 29	n	12	12	12	12	12	60
		Mean (SD)	4.27 (0.27)	4.26 (0.26)	4.08 (0.26)	4.28 (0.24)	4.22 (0.17)	4.22 (0.24)
		Min	3.8	3.8	3.6	3.9	3.9	3.6
		Median	4.20	4.25	4.05	4.25	4.20	4.20
		Max	4.8	4.8	4.6	4.7	4.6	4.8

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Potassium [mmol/L]	Day 50	n	11	12	12	12	12	59
		Mean (SD)	4.40 (0.30)	4.33 (0.24)	4.21 (0.16)	4.36 (0.29)	4.19 (0.24)	4.29 (0.25)
		Min	4.1	3.8	3.9	4.0	3.8	3.8
		Median	4.30	4.35	4.20	4.30	4.15	4.30
		Max	4.9	4.7	4.5	5.1	4.6	5.1
Sodium [mmol/L]	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	138.5 (1.7)	139.2 (1.7)	140.0 (2.0)	139.7 (1.7)	139.9 (1.7)	139.5 (1.8)
		Min	136	137	138	137	136	136
		Median	138.5	138.5	139.5	140.0	140.5	139.0
		Max	141	143	143	142	142	143
	Day 1	n	12	12	12	12	12	60
		Mean (SD)	138.3 (1.5)	139.2 (1.3)	139.0 (1.7)	139.2 (1.7)	139.7 (2.3)	139.1 (1.7)
		Min	136	137	136	137	136	136
		Median	138.0	139.0	139.0	139.0	139.5	139.0
		Max	141	141	142	142	144	144

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Sodium [mmol/L]	Day 2	n	12	12	12	12	12	60
		Mean (SD)	140.1 (1.4)	139.8 (1.9)	139.2 (1.7)	138.8 (1.6)	139.0 (1.7)	139.4 (1.7)
		Min	137	136	137	137	136	136
		Median	140.5	140.5	139.0	138.5	139.0	140.0
		Max	142	142	142	141	141	142
	Day 8	n	12	12	12	12	12	60
		Mean (SD)	139.2 (2.4)	138.6 (1.0)	140.3 (1.1)	140.3 (2.0)	139.8 (1.1)	139.6 (1.7)
		Min	134	137	138	138	138	134
		Median	139.5	138.5	140.0	140.0	139.5	139.5
		Max	142	141	142	145	141	145
	Day 29	n	12	12	12	12	12	60
		Mean (SD)	138.9 (1.7)	139.2 (2.5)	139.3 (1.6)	139.3 (1.5)	140.3 (1.5)	139.4 (1.8)
		Min	137	136	138	137	138	136
		Median	138.0	139.0	138.5	139.0	140.0	139.0
		Max	142	144	143	142	144	144

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Sodium [mmol/L]	Day 50	n	11	12	12	12	12	59
		Mean (SD)	139.5 (2.8)	140.3 (1.5)	139.6 (2.3)	139.6 (1.2)	139.3 (2.2)	139.6 (2.0)
		Min	134	139	136	138	137	134
		Median	141.0	140.0	139.5	139.5	139.0	140.0
		Max	143	144	145	142	144	145
Urea Nitrogen [mmol/L]	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	4.478 (1.159)	4.225 (1.074)	4.471 (1.607)	4.459 (0.795)	5.318 (1.420)	4.590 (1.259)
		Min	2.53	2.89	2.25	3.50	3.50	2.25
		Median	4.745	4.035	4.535	4.320	4.855	4.480
		Max	5.93	6.10	7.07	6.03	7.93	7.93
	Day 1	n	12	12	12	12	12	60
		Mean (SD)	4.863 (1.325)	4.993 (1.356)	4.748 (1.918)	4.463 (0.987)	5.043 (1.369)	4.822 (1.389)
		Min	2.71	2.43	2.18	3.11	3.03	2.18
		Median	4.870	5.230	4.105	4.590	4.730	4.695
		Max	7.93	7.64	8.32	6.35	7.96	8.32

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Urea Nitrogen [mmol/L]	Day 2	n	12	12	12	12	12	60
		Mean (SD)	4.540 (1.189)	4.385 (1.106)	4.187 (1.446)	4.388 (0.820)	4.623 (0.937)	4.424 (1.092)
		Min	2.50	2.89	1.79	3.21	2.53	1.79
		Median	4.535	4.085	4.195	4.460	4.515	4.375
		Max	6.85	6.75	6.25	6.07	6.07	6.85
	Day 8	n	12	12	12	12	12	60
		Mean (SD)	4.758 (1.088)	4.372 (1.723)	4.612 (1.701)	4.195 (1.043)	5.087 (1.674)	4.605 (1.462)
		Min	2.39	2.11	2.39	2.86	2.78	2.11
		Median	4.800	4.250	4.480	3.995	4.820	4.460
		Max	6.43	7.68	9.00	6.60	9.53	9.53
	Day 29	n	12	12	12	12	12	60
		Mean (SD)	4.373 (1.166)	4.695 (1.481)	4.472 (1.828)	4.109 (1.298)	5.312 (1.603)	4.592 (1.499)
		Min	3.32	3.00	2.43	2.39	2.93	2.39
		Median	4.105	4.360	4.015	3.715	5.355	4.280
		Max	7.43	7.57	8.71	6.57	9.10	9.10

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Urea Nitrogen [mmol/L]	Day 50	n	11	12	12	12	12	59
		Mean (SD)	4.378 (0.955)	4.356 (1.401)	4.113 (1.235)	3.871 (1.231)	4.876 (1.493)	4.318 (1.282)
		Min	2.57	2.78	2.57	2.03	2.78	2.03
		Median	4.280	4.285	3.980	4.070	4.605	4.180
		Max	6.32	6.50	7.35	5.60	8.28	8.28

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Alanine Aminotransferase [U/L]	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	25.83 (10.79)	22.25 (11.40)	16.25 (3.98)	21.44 (9.93)	21.08 (9.76)
		Min	13.0	7.0	10.0	7.0	7.0
		Median	26.50	20.50	16.00	18.00	18.00
		Max	49.0	44.0	22.0	49.0	49.0
	Day 1	n	12	12	12	36	96
		Mean (SD)	21.42 (8.40)	18.58 (7.89)	17.50 (5.90)	19.17 (7.45)	19.05 (9.19)
		Min	10.0	6.0	10.0	6.0	5.0
		Median	20.50	16.00	16.50	17.00	17.00
		Max	40.0	34.0	27.0	40.0	58.0
	Day 2	n	12	12	12	36	96
		Mean (SD)	19.92 (8.12)	18.42 (7.87)	15.83 (5.20)	18.06 (7.18)	18.60 (8.55)
		Min	10.0	5.0	8.0	5.0	5.0
		Median	18.50	17.00	15.50	16.50	17.00
		Max	36.0	33.0	23.0	36.0	48.0

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Alanine Aminotransferase [U/L]	Day 8	n	12	12	12	36	96
		Mean (SD)	22.00 (11.03)	19.75 (8.17)	15.75 (5.28)	19.17 (8.65)	19.27 (9.01)
		Min	11.0	6.0	8.0	6.0	6.0
		Median	19.00	18.00	15.00	17.50	17.00
		Max	49.0	38.0	25.0	49.0	49.0
	Day 29	n	12	12	12	36	96
		Mean (SD)	23.42 (9.98)	20.00 (9.30)	19.92 (13.81)	21.11 (11.01)	20.81 (11.73)
		Min	10.0	5.0	11.0	5.0	5.0
		Median	22.00	18.50	15.50	18.00	17.00
		Max	42.0	40.0	62.0	62.0	65.0
	Day 50	n	10	11	12	33	92
		Mean (SD)	23.20 (10.45)	19.95 (11.48)	18.00 (7.08)	20.23 (9.68)	20.03 (10.74)
		Min	9.0	2.5	9.0	2.5	2.5
		Median	21.00	18.00	15.50	17.00	17.00
		Max	37.0	48.0	30.0	48.0	68.0

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Albumin [g/L]	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	44.6 (1.8)	43.9 (1.8)	44.7 (2.1)	44.4 (1.9)	44.7 (2.1)
		Min	43	41	41	41	40
		Median	44.0	44.0	44.5	44.0	45.0
		Max	49	47	49	49	49
	Day 1	n	12	12	12	36	96
		Mean (SD)	43.1 (2.2)	40.6 (2.5)	43.4 (2.5)	42.4 (2.6)	42.3 (2.5)
		Min	40	36	39	36	36
		Median	43.0	40.5	43.5	43.0	42.0
		Max	48	44	48	48	49
	Day 2	n	12	12	12	36	96
		Mean (SD)	42.5 (1.9)	41.4 (1.7)	42.9 (1.3)	42.3 (1.7)	42.3 (2.2)
		Min	39	39	40	39	38
		Median	42.5	42.0	43.0	42.0	42.0
		Max	46	44	45	46	47

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Albumin [g/L]	Day 8	n	12	12	12	36	96
		Mean (SD)	43.8 (2.2)	42.2 (2.0)	42.4 (2.2)	42.8 (2.2)	42.7 (2.3)
		Min	40	39	38	38	38
		Median	44.0	42.0	43.0	43.0	42.5
		Max	47	46	46	47	50
	Day 29	n	12	12	12	36	96
		Mean (SD)	44.4 (1.5)	42.0 (2.0)	42.7 (1.5)	43.0 (1.9)	42.2 (2.1)
		Min	42	39	41	39	37
		Median	44.5	42.0	42.0	43.0	42.0
		Max	47	46	45	47	47
	Day 50	n	10	11	12	33	92
		Mean (SD)	42.3 (1.8)	42.9 (2.0)	44.1 (1.6)	43.2 (1.9)	42.6 (2.1)
		Min	40	40	41	40	38
		Median	42.0	42.0	44.0	43.0	43.0
		Max	45	47	46	47	48

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Alkaline Phosphatase [U/L]	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	78.4 (25.8)	59.6 (10.1)	77.4 (25.2)	71.8 (22.8)	63.8 (19.2)
		Min	51	42	44	42	37
		Median	74.0	59.0	71.5	66.5	59.5
		Max	145	76	142	145	145
	Day 1	n	12	12	12	36	96
		Mean (SD)	77.9 (32.8)	55.3 (9.7)	80.3 (26.9)	71.2 (27.0)	61.8 (20.9)
		Min	50	44	47	44	34
		Median	72.0	53.0	73.0	65.5	56.5
		Max	169	74	151	169	169
	Day 2	n	12	12	12	36	96
		Mean (SD)	74.5 (27.2)	59.4 (10.2)	79.8 (26.6)	71.2 (23.8)	62.8 (19.8)
		Min	46	42	48	42	37
		Median	69.5	60.0	71.0	67.0	60.0
		Max	144	79	153	153	153

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Alkaline Phosphatase [U/L]	Day 8	n	12	12	12	36	96
		Mean (SD)	82.4 (36.4)	57.3 (10.3)	76.9 (22.0)	72.2 (26.9)	63.5 (21.4)
		Min	52	40	42	40	36
		Median	79.0	54.5	72.0	69.0	58.5
		Max	186	75	130	186	186
	Day 29	n	12	12	12	36	96
		Mean (SD)	82.7 (28.3)	58.9 (10.1)	78.7 (25.0)	73.4 (24.3)	64.1 (21.2)
		Min	53	39	42	39	34
		Median	81.0	57.5	73.5	68.5	59.5
		Max	159	77	140	159	159
	Day 50	n	10	11	12	33	92
		Mean (SD)	69.6 (13.9)	59.1 (9.8)	81.9 (27.0)	70.6 (20.7)	62.2 (18.2)
		Min	48	44	49	44	34
		Median	71.5	56.0	74.5	70.0	56.0
		Max	93	74	153	153	153

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Amylase [U/L]	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	71.9 (23.5)	61.6 (15.3)	65.4 (20.5)	66.3 (19.9)	60.4 (21.6)
		Min	38	39	47	38	20
		Median	74.5	64.5	60.5	64.0	56.5
		Max	108	90	108	108	131
	Day 1	n	12	12	12	36	96
		Mean (SD)	73.6 (27.0)	61.8 (14.0)	65.6 (21.8)	67.0 (21.6)	59.2 (21.7)
		Min	43	34	43	34	20
		Median	69.5	60.5	63.5	64.5	56.0
		Max	126	80	124	126	126
	Day 2	n	12	12	12	36	96
		Mean (SD)	76.4 (27.1)	62.7 (14.9)	62.8 (21.7)	67.3 (22.2)	59.1 (21.5)
		Min	42	36	43	36	19
		Median	76.5	65.0	58.0	64.5	54.0
		Max	129	81	122	129	129

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Amylase [U/L]	Day 8	n	12	12	12	36	96
		Mean (SD)	78.2 (29.0)	82.3 (51.3)	66.8 (23.2)	75.8 (36.1)	62.9 (29.6)
		Min	45	40	40	40	17
		Median	72.5	67.0	62.5	65.0	58.0
		Max	139	229	125	229	229
	Day 29	n	12	12	12	36	96
		Mean (SD)	79.7 (24.2)	64.3 (16.3)	64.8 (21.9)	69.6 (21.7)	60.6 (21.4)
		Min	44	36	45	36	20
		Median	77.0	61.0	59.0	61.5	58.0
		Max	120	91	116	120	120
	Day 50	n	10	11	12	33	92
		Mean (SD)	76.6 (32.1)	67.8 (17.8)	64.9 (22.7)	69.4 (24.3)	59.0 (22.5)
		Min	45	43	42	42	19
		Median	64.5	64.0	58.0	61.0	54.5
		Max	137	98	116	137	137

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Aspartate Aminotransferase [U/L]	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	24.7 (5.8)	24.8 (10.2)	19.6 (3.4)	23.0 (7.3)	21.3 (6.0)
		Min	15	18	15	15	11
		Median	24.0	21.5	20.5	22.5	20.0
		Max	36	55	24	55	55
	Day 1	n	12	12	12	36	96
		Mean (SD)	20.6 (4.3)	20.3 (3.9)	20.0 (4.0)	20.3 (3.9)	20.5 (7.3)
		Min	13	14	15	13	11
		Median	20.0	19.5	19.0	19.0	19.0
		Max	29	28	27	29	62
	Day 2	n	12	12	12	36	96
		Mean (SD)	18.4 (3.3)	19.6 (4.0)	18.4 (3.4)	18.8 (3.5)	19.3 (5.8)
		Min	12	16	14	12	11
		Median	18.5	18.0	18.5	18.0	18.0
		Max	23	29	24	29	49

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Aspartate Aminotransferase [U/L]	Day 8	n	12	12	12	36	96
		Mean (SD)	22.3 (4.7)	21.6 (4.2)	20.5 (3.4)	21.5 (4.1)	20.8 (6.1)
		Min	12	15	16	12	11
		Median	24.5	20.5	20.5	21.0	20.0
		Max	27	30	26	30	47
	Day 29	n	12	12	12	36	96
		Mean (SD)	23.7 (5.0)	23.7 (4.5)	21.3 (5.1)	22.9 (4.9)	21.2 (6.8)
		Min	15	18	15	15	11
		Median	23.5	23.0	21.0	22.5	20.0
		Max	32	31	34	34	51
	Day 50	n	10	11	12	33	92
		Mean (SD)	23.0 (5.6)	22.2 (5.6)	21.0 (6.4)	22.0 (5.8)	21.2 (6.0)
		Min	15	17	12	12	10
		Median	23.0	21.0	20.0	21.0	20.0
		Max	34	34	37	37	45

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Bilirubin (Serum) [µmol/L]	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	8.76 (3.10)	9.49 (3.84)	8.78 (5.38)	9.01 (4.11)	8.93 (4.34)
		Min	4.1	4.6	1.3	1.3	1.3
		Median	7.95	8.80	7.10	7.55	7.95
		Max	14.0	16.2	18.8	18.8	21.2
	Day 1	n	12	12	12	36	96
		Mean (SD)	8.18 (3.16)	8.19 (3.48)	8.23 (3.25)	8.20 (3.20)	8.10 (4.40)
		Min	3.6	3.8	3.9	3.6	2.7
		Median	8.05	7.90	8.15	8.05	7.20
		Max	14.0	14.4	15.4	15.4	27.9
	Day 2	n	12	12	12	36	96
		Mean (SD)	8.40 (3.77)	9.93 (4.02)	12.19 (5.43)	10.17 (4.62)	9.94 (5.73)
		Min	1.3	5.1	6.8	1.3	1.3
		Median	7.95	9.75	10.10	8.95	8.50
		Max	14.5	18.0	22.1	22.1	40.0

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Bilirubin (Serum) [µmol/L]	Day 8	n	12	12	12	36	96
		Mean (SD)	7.38 (2.78)	7.14 (3.23)	7.16 (3.27)	7.23 (3.02)	7.32 (3.95)
		Min	3.1	1.3	1.3	1.3	1.3
		Median	6.95	8.55	6.40	6.95	6.30
		Max	12.3	11.8	12.8	12.8	22.1
	Day 29	n	12	12	12	36	96
		Mean (SD)	7.24 (3.27)	8.58 (2.85)	8.38 (3.50)	8.07 (3.18)	7.59 (3.78)
		Min	1.3	4.6	4.1	1.3	1.3
		Median	6.70	9.90	7.50	7.70	6.40
		Max	14.5	12.3	15.4	15.4	20.3
	Day 50	n	10	11	12	33	92
		Mean (SD)	8.36 (4.03)	7.75 (1.87)	6.84 (3.05)	7.60 (3.04)	7.94 (4.01)
		Min	1.3	5.1	2.6	1.3	1.3
		Median	8.15	7.40	6.75	7.20	7.40
		Max	15.6	11.6	12.5	15.6	20.3

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
C Reactive Protein [mg/L]	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	1.550 (1.083)	1.783 (1.898)	1.083 (0.506)	1.472 (1.291)	1.102 (1.323)
		Min	0.40	0.40	0.30	0.30	0.15
		Median	1.200	1.400	0.950	1.250	0.800
		Max	4.00	7.50	1.90	7.50	8.70
	Day 1	n	12	12	12	36	96
		Mean (SD)	1.583 (1.230)	1.233 (0.626)	1.550 (1.071)	1.456 (0.992)	1.146 (1.175)
		Min	0.40	0.30	0.30	0.30	0.15
		Median	1.450	1.200	1.250	1.200	0.800
		Max	4.60	2.60	4.20	4.60	7.40
	Day 2	n	12	12	12	36	96
		Mean (SD)	1.683 (0.926)	1.933 (0.756)	4.875 (6.479)	2.831 (3.975)	2.033 (2.774)
		Min	0.40	0.50	0.50	0.40	0.15
		Median	1.800	1.900	2.550	1.950	1.550
		Max	3.80	3.00	23.90	23.90	23.90

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
C Reactive Protein [mg/L]	Day 8	n	12	12	12	36	96
		Mean (SD)	1.558 (1.198)	1.817 (2.009)	1.692 (1.074)	1.689 (1.447)	1.623 (3.414)
		Min	0.40	0.30	0.30	0.30	0.15
		Median	1.000	1.350	1.300	1.250	0.950
		Max	3.80	7.90	4.10	7.90	31.60
	Day 29	n	12	12	12	36	96
		Mean (SD)	1.992 (1.571)	1.617 (0.975)	2.417 (1.307)	2.008 (1.312)	1.516 (1.308)
		Min	0.40	0.40	0.50	0.40	0.15
		Median	1.400	1.450	2.500	1.550	1.100
		Max	6.30	3.20	5.10	6.30	6.30
	Day 50	n	10	11	12	33	92
		Mean (SD)	3.190 (5.273)	2.900 (2.583)	1.467 (0.774)	2.467 (3.273)	1.696 (2.360)
		Min	0.50	0.30	0.40	0.30	0.10
		Median	1.350	1.900	1.300	1.500	0.900
		Max	17.90	8.20	2.80	17.90	17.90

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Calcium [mmol/L]	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	2.388 (0.080)	2.338 (0.068)	2.423 (0.179)	2.383 (0.121)	2.367 (0.096)
		Min	2.28	2.23	2.27	2.23	2.18
		Median	2.375	2.330	2.385	2.370	2.365
		Max	2.51	2.45	2.95	2.95	2.95
	Day 1	n	12	12	12	36	96
		Mean (SD)	2.345 (0.089)	2.308 (0.055)	2.448 (0.175)	2.367 (0.129)	2.322 (0.108)
		Min	2.22	2.24	2.29	2.22	2.11
		Median	2.345	2.310	2.400	2.355	2.315
		Max	2.50	2.38	2.96	2.96	2.96
	Day 2	n	12	12	12	36	96
		Mean (SD)	2.301 (0.074)	2.324 (0.066)	2.384 (0.168)	2.336 (0.115)	2.317 (0.087)
		Min	2.22	2.23	2.28	2.22	2.19
		Median	2.300	2.305	2.320	2.305	2.300
		Max	2.47	2.43	2.88	2.88	2.88

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Calcium [mmol/L]	Day 8	n	12	12	12	36	96
		Mean (SD)	2.385 (0.107)	2.320 (0.070)	2.400 (0.195)	2.368 (0.135)	2.329 (0.104)
		Min	2.25	2.21	2.23	2.21	2.12
		Median	2.345	2.320	2.355	2.345	2.330
		Max	2.57	2.43	3.00	3.00	3.00
	Day 29	n	12	12	12	36	96
		Mean (SD)	2.380 (0.046)	2.336 (0.066)	2.391 (0.183)	2.369 (0.115)	2.321 (0.103)
		Min	2.31	2.26	2.23	2.23	2.08
		Median	2.390	2.325	2.340	2.345	2.310
		Max	2.47	2.50	2.91	2.91	2.91
	Day 50	n	10	11	12	33	92
		Mean (SD)	2.306 (0.074)	2.326 (0.099)	2.377 (0.154)	2.338 (0.117)	2.321 (0.096)
		Min	2.20	2.22	2.20	2.20	2.12
		Median	2.310	2.300	2.340	2.320	2.310
		Max	2.43	2.53	2.83	2.83	2.83

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Creatinine [µmol/L]	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	72.93 (10.68)	77.19 (14.73)	68.35 (15.42)	72.83 (13.86)	76.40 (14.48)
		Min	55.7	55.7	43.3	43.3	43.3
		Median	70.25	74.25	68.10	70.70	73.40
		Max	96.4	108.7	97.2	108.7	110.5
	Day 1	n	12	12	12	36	96
		Mean (SD)	75.43 (10.36)	76.90 (12.09)	71.18 (16.12)	74.50 (12.94)	75.34 (12.69)
		Min	57.5	59.2	48.6	48.6	48.6
		Median	75.55	74.70	71.15	73.40	74.70
		Max	94.6	101.7	101.7	101.7	103.4
	Day 2	n	12	12	12	36	96
		Mean (SD)	76.09 (13.50)	74.48 (10.66)	67.43 (15.28)	72.66 (13.45)	75.87 (13.42)
		Min	54.8	59.2	46.0	46.0	46.0
		Median	72.95	72.45	64.10	69.40	75.55
		Max	96.4	90.2	100.8	100.8	104.3

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Creatinine [µmol/L]	Day 8	n	12	12	12	36	96
		Mean (SD)	78.09 (11.01)	74.93 (10.83)	67.70 (17.04)	73.57 (13.63)	74.56 (13.28)
		Min	62.8	61.0	45.1	45.1	45.1
		Median	78.25	72.95	68.10	72.50	73.40
		Max	102.5	93.7	108.7	108.7	108.7
	Day 29	n	12	12	12	36	96
		Mean (SD)	75.53 (9.92)	77.42 (9.21)	69.83 (15.64)	74.26 (12.05)	74.69 (13.07)
		Min	58.3	61.9	47.7	47.7	47.7
		Median	75.15	76.90	66.75	74.70	74.30
		Max	95.5	90.2	107.8	107.8	107.8
	Day 50	n	10	11	12	33	92
		Mean (SD)	79.48 (11.01)	79.15 (13.52)	71.89 (13.71)	76.61 (13.00)	75.76 (12.67)
		Min	67.2	59.2	49.5	49.5	49.5
		Median	76.50	79.60	71.60	74.30	74.30
		Max	98.1	99.0	102.5	102.5	107.8

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Ferritin [µg/L]	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	142.34 (84.17)	94.52 (48.64)	103.97 (68.56)	113.61 (69.91)	84.93 (66.07)
		Min	26.5	21.0	15.5	15.5	6.4
		Median	151.60	86.40	71.05	93.55	59.50
		Max	288.2	184.4	202.1	288.2	288.2
	Day 1	n	12	12	12	36	96
		Mean (SD)	140.22 (90.79)	87.24 (48.45)	104.74 (72.83)	110.73 (74.13)	79.41 (63.70)
		Min	32.2	17.9	20.1	17.9	8.4
		Median	150.70	82.60	80.75	88.25	52.85
		Max	280.3	158.8	234.2	280.3	280.3
	Day 2	n	12	12	12	36	96
		Mean (SD)	134.08 (91.91)	89.35 (45.86)	110.28 (64.53)	111.24 (70.48)	81.92 (62.44)
		Min	31.0	26.5	33.0	26.5	7.3
		Median	128.85	82.40	88.50	96.55	62.80
		Max	292.3	154.5	222.5	292.3	292.3

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Ferritin [µg/L]	Day 8	n	12	12	12	36	96
		Mean (SD)	132.95 (88.10)	81.73 (42.08)	104.36 (62.63)	106.34 (68.41)	77.71 (61.03)
		Min	31.9	27.0	21.3	21.3	7.0
		Median	133.85	71.25	80.80	89.80	58.55
		Max	291.9	143.7	200.4	291.9	291.9
	Day 29	n	12	12	12	36	96
		Mean (SD)	134.61 (96.55)	80.08 (38.87)	104.86 (59.71)	106.52 (70.96)	73.78 (59.78)
		Min	26.1	36.3	21.2	21.2	6.0
		Median	132.40	76.15	86.60	86.60	54.80
		Max	294.7	154.9	195.1	294.7	294.7
	Day 50	n	10	11	12	33	92
		Mean (SD)	96.05 (75.37)	66.55 (38.63)	69.47 (45.27)	76.55 (54.23)	55.10 (46.59)
		Min	18.9	18.3	10.3	10.3	5.7
		Median	80.55	60.40	54.55	60.40	38.80
		Max	226.0	133.5	134.3	226.0	226.0

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Follicle Stimulating Hormone [IU/L]	Day -30 to 0	n	2	6	5	13	46
		Mean (SD)	64.40 (-)	65.07 (11.06)	86.40 (10.67)	73.17 (14.42)	38.26 (39.46)
		Min	62.6	43.9	76.3	43.9	1.9
		Median	64.40	67.45	85.40	71.70	19.45
		Max	66.2	75.3	101.7	101.7	162.7
Gamma Glutamyl Transferase [U/L]	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	27.3 (17.3)	22.5 (12.3)	18.2 (9.1)	22.7 (13.5)	18.7 (11.2)
		Min	10	10	8	8	7
		Median	20.5	18.0	15.0	17.0	16.0
		Max	62	47	41	62	62
	Day 1	n	12	12	12	36	96
		Mean (SD)	23.7 (14.0)	20.3 (11.2)	19.5 (9.4)	21.2 (11.5)	17.3 (9.9)
		Min	9	9	9	9	6
		Median	18.0	16.5	17.0	17.5	14.0
		Max	50	45	41	50	50

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Gamma Glutamyl Transferase [U/L]	Day 2	n	12	12	12	36	96
		Mean (SD)	22.5 (13.4)	20.3 (10.1)	18.3 (9.3)	20.4 (10.9)	16.9 (9.5)
		Min	8	9	9	8	6
		Median	18.0	17.0	15.0	16.0	14.0
		Max	48	42	40	48	50
	Day 8	n	12	12	12	36	96
		Mean (SD)	23.3 (12.9)	20.7 (11.5)	20.1 (10.7)	21.4 (11.5)	17.7 (10.1)
		Min	9	10	8	8	6
		Median	19.0	17.0	17.5	17.5	14.5
		Max	48	48	44	48	54
	Day 29	n	12	12	12	36	96
		Mean (SD)	24.3 (13.0)	22.2 (14.1)	22.3 (16.5)	22.9 (14.2)	18.6 (11.7)
		Min	9	9	8	8	7
		Median	19.0	18.0	15.0	18.0	15.0
		Max	51	58	62	62	62

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Gamma Glutamyl Transferase [U/L]	Day 50	n	10	11	12	33	92
		Mean (SD)	26.8 (16.9)	24.3 (17.0)	21.3 (13.4)	23.9 (15.4)	18.6 (12.2)
		Min	9	11	9	9	6
		Median	19.5	18.0	15.5	17.0	15.0
		Max	61	71	50	71	71
Glucose (Blood) [mmol/L]	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	5.398 (0.275)	5.867 (0.386)	5.422 (0.396)	5.562 (0.410)	5.424 (0.413)
		Min	5.00	5.34	4.84	4.84	4.61
		Median	5.420	5.810	5.395	5.560	5.390
		Max	5.78	6.51	6.00	6.51	6.56
	Day 1	n	12	12	12	36	96
		Mean (SD)	5.478 (0.756)	5.948 (0.485)	5.254 (0.528)	5.560 (0.654)	5.458 (0.580)
		Min	4.73	5.17	4.45	4.45	4.06
		Median	5.255	5.950	5.200	5.475	5.340
		Max	7.62	6.67	6.34	7.62	7.62

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Glucose (Blood) [mmol/L]	Day 2	n	12	12	12	36	96
		Mean (SD)	5.249 (0.475)	5.857 (0.524)	5.286 (0.525)	5.464 (0.569)	5.430 (0.525)
		Min	4.17	4.95	4.34	4.17	4.17
		Median	5.200	5.785	5.335	5.390	5.365
		Max	6.06	6.67	6.00	6.67	7.17
	Day 8	n	12	12	12	36	96
		Mean (SD)	5.413 (0.279)	5.847 (0.407)	5.311 (0.349)	5.524 (0.413)	5.399 (0.546)
		Min	5.06	5.23	4.73	4.73	4.23
		Median	5.395	5.945	5.340	5.450	5.365
		Max	6.06	6.39	5.84	6.39	8.28
	Day 29	n	12	12	12	36	96
		Mean (SD)	5.374 (0.386)	5.891 (0.656)	5.454 (0.418)	5.573 (0.538)	5.394 (0.495)
		Min	4.67	4.73	4.84	4.67	4.39
		Median	5.420	5.840	5.395	5.590	5.340
		Max	6.06	7.12	6.12	7.12	7.12

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Glucose (Blood) [mmol/L]	Day 50	n	10	11	12	33	92
		Mean (SD)	5.470 (0.380)	5.782 (0.448)	5.492 (0.420)	5.582 (0.430)	5.394 (0.443)
		Min	5.00	5.12	4.84	4.84	4.50
		Median	5.335	5.780	5.620	5.620	5.340
		Max	5.95	6.73	6.06	6.73	6.84
Lipase [U/L]	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	33.8 (12.7)	38.6 (10.9)	39.9 (12.4)	37.4 (12.0)	35.2 (15.7)
		Min	23	27	23	23	15
		Median	29.0	35.5	36.5	34.0	32.5
		Max	64	67	61	67	133
	Day 1	n	12	12	12	36	96
		Mean (SD)	39.6 (21.4)	43.4 (14.3)	40.4 (13.9)	41.1 (16.5)	37.1 (15.6)
		Min	23	28	20	20	14
		Median	30.5	37.0	38.5	35.5	34.0
		Max	93	75	64	93	93

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Lipase [U/L]	Day 2	n	12	12	12	36	96
		Mean (SD)	41.1 (19.0)	40.3 (10.6)	36.7 (13.2)	39.4 (14.4)	35.2 (15.1)
		Min	26	29	17	17	12
		Median	32.5	36.0	36.0	36.0	33.0
		Max	81	64	65	81	81
	Day 8	n	12	12	12	36	96
		Mean (SD)	38.5 (11.1)	88.8 (145.6)	41.7 (12.9)	56.3 (85.4)	43.6 (55.2)
		Min	23	34	24	23	14
		Median	38.0	43.5	39.0	39.0	35.0
		Max	58	550	70	550	550
	Day 29	n	12	12	12	36	96
		Mean (SD)	40.2 (14.2)	43.1 (13.3)	42.5 (15.0)	41.9 (13.8)	39.1 (18.6)
		Min	23	27	24	23	15
		Median	38.5	39.5	40.0	39.5	35.5
		Max	63	68	77	77	160

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Lipase [U/L]	Day 50	n	10	11	12	33	92
		Mean (SD)	46.5 (26.1)	44.2 (13.9)	42.1 (14.1)	44.1 (18.0)	37.8 (15.4)
		Min	27	32	21	21	14
		Median	35.5	36.0	39.0	37.0	35.0
		Max	110	67	69	110	110
Potassium [mmol/L]	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	4.56 (0.36)	4.44 (0.16)	4.44 (0.42)	4.48 (0.33)	4.42 (0.29)
		Min	4.1	4.2	4.1	4.1	3.9
		Median	4.50	4.40	4.40	4.40	4.40
		Max	5.4	4.8	5.6	5.6	5.6
	Day 1	n	12	12	12	36	96
		Mean (SD)	4.38 (0.17)	4.28 (0.25)	4.58 (0.32)	4.41 (0.27)	4.26 (0.32)
		Min	4.1	4.0	4.1	4.0	3.5
		Median	4.40	4.15	4.55	4.40	4.20
		Max	4.7	4.7	5.2	5.2	5.8

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Potassium [mmol/L]	Day 2	n	12	12	12	36	96
		Mean (SD)	4.43 (0.25)	4.51 (0.30)	4.51 (0.39)	4.48 (0.31)	4.40 (0.30)
		Min	4.1	4.0	4.1	4.0	3.7
		Median	4.50	4.50	4.35	4.45	4.40
		Max	4.8	5.1	5.4	5.4	5.4
	Day 8	n	12	12	12	36	96
		Mean (SD)	4.72 (0.44)	4.50 (0.35)	4.59 (0.32)	4.60 (0.37)	4.40 (0.33)
		Min	4.0	3.9	4.2	3.9	3.8
		Median	4.70	4.50	4.45	4.60	4.35
		Max	5.8	4.9	5.3	5.8	5.8
	Day 29	n	12	12	12	36	96
		Mean (SD)	4.34 (0.22)	4.48 (0.37)	4.56 (0.30)	4.46 (0.31)	4.31 (0.29)
		Min	4.0	4.2	4.1	4.0	3.6
		Median	4.30	4.45	4.55	4.40	4.30
		Max	4.9	5.6	5.2	5.6	5.6

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Potassium [mmol/L]	Day 50	n	10	11	12	33	92
		Mean (SD)	4.42 (0.32)	4.51 (0.44)	4.59 (0.25)	4.51 (0.34)	4.37 (0.30)
		Min	3.6	3.9	4.2	3.6	3.6
		Median	4.40	4.50	4.55	4.50	4.40
		Max	4.7	5.4	5.0	5.4	5.4
Sodium [mmol/L]	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	140.3 (2.1)	140.1 (1.6)	139.8 (1.8)	140.0 (1.8)	139.7 (1.8)
		Min	137	138	137	137	136
		Median	140.5	140.0	139.5	140.0	140.0
		Max	144	144	143	144	144
	Day 1	n	12	12	12	36	96
		Mean (SD)	139.1 (2.1)	139.9 (2.5)	140.9 (1.9)	140.0 (2.2)	139.4 (2.0)
		Min	136	134	138	134	134
		Median	139.0	140.5	141.0	140.0	139.0
		Max	142	143	145	145	145

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Sodium [mmol/L]	Day 2	n	12	12	12	36	96
		Mean (SD)	140.0 (2.4)	140.6 (1.3)	138.9 (2.0)	139.8 (2.0)	139.5 (1.8)
		Min	135	138	136	135	135
		Median	141.0	141.0	138.5	140.0	140.0
		Max	143	143	143	143	143
	Day 8	n	12	12	12	36	96
		Mean (SD)	139.9 (2.8)	140.7 (1.4)	139.3 (1.1)	140.0 (2.0)	139.8 (1.8)
		Min	133	138	138	133	133
		Median	140.5	141.0	140.0	140.0	140.0
		Max	144	143	141	144	145
	Day 29	n	12	12	12	36	96
		Mean (SD)	141.1 (2.1)	140.5 (1.4)	138.9 (1.7)	140.2 (1.9)	139.7 (1.9)
		Min	137	138	135	135	135
		Median	141.5	140.0	139.5	140.0	140.0
		Max	144	143	141	144	144

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Sodium [mmol/L]	Day 50	n	10	11	12	33	92
		Mean (SD)	141.1 (1.7)	140.5 (2.0)	139.2 (1.7)	140.2 (1.9)	139.8 (2.0)
		Min	139	136	137	136	134
		Median	141.0	140.0	139.0	140.0	140.0
		Max	144	143	143	144	145
Urea Nitrogen [mmol/L]	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	4.992 (1.458)	5.403 (1.605)	5.254 (1.426)	5.216 (1.465)	4.825 (1.367)
		Min	2.82	3.39	3.53	2.82	2.25
		Median	4.890	5.070	5.035	4.945	4.745
		Max	8.18	8.64	7.78	8.64	8.64
	Day 1	n	12	12	12	36	96
		Mean (SD)	5.522 (1.400)	5.361 (1.298)	5.158 (1.430)	5.347 (1.346)	5.019 (1.390)
		Min	3.39	3.00	2.71	2.71	2.18
		Median	5.250	5.140	5.265	5.195	4.910
		Max	8.43	7.78	6.78	8.43	8.43

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Urea Nitrogen [mmol/L]	Day 2	n	12	12	12	36	96
		Mean (SD)	5.509 (0.725)	4.804 (1.472)	4.473 (1.032)	4.929 (1.172)	4.614 (1.143)
		Min	4.61	3.43	2.96	2.96	1.79
		Median	5.215	4.210	4.500	4.960	4.660
		Max	6.60	7.93	6.28	7.93	7.93
	Day 8	n	12	12	12	36	96
		Mean (SD)	5.293 (1.391)	5.183 (1.237)	5.480 (1.495)	5.318 (1.344)	4.872 (1.454)
		Min	3.89	3.36	3.61	3.36	2.11
		Median	4.945	5.035	5.465	5.090	4.680
		Max	9.10	7.71	8.71	9.10	9.53
	Day 29	n	12	12	12	36	96
		Mean (SD)	5.827 (3.166)	5.038 (1.267)	5.001 (0.981)	5.288 (2.026)	4.853 (1.738)
		Min	3.78	3.46	3.61	3.46	2.39
		Median	4.800	4.835	4.890	4.835	4.515
		Max	15.35	8.21	6.82	15.35	15.35

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.2-3: Laboratory: Descriptive statistics, continuous (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Urea Nitrogen [mmol/L]	Day 50	n	10	11	12	33	92
		Mean (SD)	6.114 (1.571)	5.270 (0.904)	5.411 (1.907)	5.577 (1.527)	4.769 (1.496)
		Min	3.53	3.03	2.78	2.78	2.03
		Median	5.675	5.430	5.445	5.600	4.730
		Max	8.64	6.35	9.07	9.07	9.07

SD is only calculated if values of at least 3 subjects are available. Follicle Stimulating Hormone is only collected for women.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.3-3: Laboratory: Descriptive statistics, continuous (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
pH	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	5.88 (0.93)	6.17 (1.01)	5.50 (1.00)	5.83 (0.91)	6.04 (0.96)	5.88 (0.96)
		Min	5.0	5.0	5.0	5.0	5.0	5.0
		Median	5.75	6.25	5.00	5.50	6.25	5.50
		Max	7.0	8.0	8.0	7.0	7.0	8.0
	Day 1	n	12	12	12	12	12	60
		Mean (SD)	5.67 (0.86)	6.13 (1.09)	5.50 (0.90)	6.00 (1.11)	6.38 (1.15)	5.93 (1.04)
		Min	5.0	5.0	5.0	5.0	5.0	5.0
		Median	5.00	6.00	5.00	5.75	6.00	6.00
		Max	7.0	8.0	7.0	8.0	8.0	8.0
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	6.08 (0.85)	6.00 (0.95)	5.71 (0.78)	5.71 (0.92)	6.13 (1.15)	5.93 (0.92)
		Min	5.0	5.0	5.0	5.0	5.0	5.0
		Median	6.50	6.00	5.50	5.50	6.25	6.00
		Max	7.0	7.0	7.0	8.0	8.0	8.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.3-3: Laboratory: Descriptive statistics, continuous (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
pH	Day 8	n	12	12	12	12	12	60
		Mean (SD)	5.67 (0.75)	6.13 (0.88)	5.58 (0.76)	5.63 (0.83)	6.08 (1.14)	5.82 (0.89)
		Min	5.0	5.0	5.0	5.0	5.0	5.0
		Median	5.50	6.50	5.00	5.00	6.00	6.00
		Max	7.0	7.0	7.0	7.0	8.0	8.0
	Day 29	n	12	12	12	12	12	60
		Mean (SD)	6.00 (0.93)	6.13 (1.17)	5.46 (0.72)	5.46 (0.84)	6.21 (0.92)	5.85 (0.95)
		Min	5.0	5.0	5.0	5.0	5.0	5.0
		Median	6.25	6.00	5.00	5.00	6.25	5.50
		Max	7.0	8.0	7.0	7.0	8.0	8.0
	Day 50	n	11	12	12	12	12	59
		Mean (SD)	5.41 (0.74)	6.29 (1.05)	5.58 (0.76)	5.63 (0.93)	6.25 (1.03)	5.84 (0.96)
		Min	5.0	5.0	5.0	5.0	5.0	5.0
		Median	5.00	6.75	5.00	5.00	6.50	5.00
		Max	7.0	8.0	7.0	7.0	8.0	8.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.3-3: Laboratory: Descriptive statistics, continuous (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Specific Gravity	Day -30 to 0	n	12	12	12	12	12	60
		Mean (SD)	1.0104 (0.0081)	1.0079 (0.0058)	1.0167 (0.0054)	1.0121 (0.0062)	1.0125 (0.0075)	1.0119 (0.0071)
		Min	1.000	1.000	1.005	1.005	1.005	1.000
		Median	1.0125	1.0050	1.0175	1.0125	1.0125	1.0150
		Max	1.020	1.015	1.025	1.020	1.025	1.025
	Day 1	n	12	12	12	12	12	60
		Mean (SD)	1.0154 (0.0054)	1.0113 (0.0061)	1.0146 (0.0072)	1.0104 (0.0075)	1.0129 (0.0069)	1.0129 (0.0067)
		Min	1.005	1.005	1.005	1.000	1.005	1.000
		Median	1.0150	1.0100	1.0150	1.0100	1.0125	1.0150
		Max	1.020	1.025	1.025	1.025	1.020	1.025
	Day 2	n	12	12	12	12	12	60
		Mean (SD)	1.0133 (0.0069)	1.0146 (0.0054)	1.0158 (0.0073)	1.0133 (0.0044)	1.0133 (0.0054)	1.0141 (0.0059)
		Min	1.000	1.005	1.005	1.005	1.005	1.000
		Median	1.0150	1.0150	1.0200	1.0150	1.0150	1.0150
		Max	1.025	1.020	1.025	1.020	1.020	1.025

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.3-3: Laboratory: Descriptive statistics, continuous (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Specific Gravity	Day 8	n	12	12	12	12	12	60
		Mean (SD)	1.0150 (0.0060)	1.0129 (0.0062)	1.0154 (0.0072)	1.0121 (0.0066)	1.0129 (0.0078)	1.0137 (0.0067)
		Min	1.005	1.005	1.005	1.005	1.005	1.005
		Median	1.0150	1.0100	1.0150	1.0125	1.0100	1.0150
		Max	1.025	1.025	1.030	1.025	1.025	1.030
	Day 29	n	12	12	12	12	12	60
		Mean (SD)	1.0121 (0.0072)	1.0125 (0.0069)	1.0179 (0.0086)	1.0163 (0.0043)	1.0138 (0.0068)	1.0145 (0.0071)
		Min	1.000	1.005	1.000	1.005	1.005	1.000
		Median	1.0125	1.0125	1.0200	1.0150	1.0150	1.0150
		Max	1.020	1.025	1.030	1.020	1.025	1.030
	Day 50	n	11	12	12	12	12	59
		Mean (SD)	1.0155 (0.0057)	1.0113 (0.0068)	1.0129 (0.0072)	1.0138 (0.0083)	1.0113 (0.0074)	1.0129 (0.0071)
		Min	1.005	1.005	1.005	1.005	1.005	1.005
		Median	1.0150	1.0100	1.0125	1.0150	1.0075	1.0150
		Max	1.025	1.020	1.025	1.025	1.025	1.025

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.3-3: Laboratory: Descriptive statistics, continuous (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
pH	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	5.83 (1.11)	5.63 (0.93)	5.58 (1.00)	5.68 (0.99)	5.81 (0.97)
		Min	5.0	5.0	5.0	5.0	5.0
		Median	5.00	5.00	5.00	5.00	5.00
		Max	8.0	7.0	8.0	8.0	8.0
	Day 1	n	12	12	12	36	96
		Mean (SD)	6.00 (1.00)	5.96 (1.10)	5.42 (0.76)	5.79 (0.97)	5.88 (1.02)
		Min	5.0	5.0	5.0	5.0	5.0
		Median	6.25	5.50	5.00	5.00	5.00
		Max	8.0	8.0	7.0	8.0	8.0
	Day 2	n	12	12	12	36	96
		Mean (SD)	5.50 (0.90)	6.04 (1.14)	5.88 (0.83)	5.81 (0.97)	5.88 (0.94)
		Min	5.0	5.0	5.0	5.0	5.0
		Median	5.00	5.75	6.00	5.00	6.00
		Max	7.0	8.0	7.0	8.0	8.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.3-3: Laboratory: Descriptive statistics, continuous (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
pH	Day 8	n	12	12	12	36	96
		Mean (SD)	6.33 (1.05)	5.67 (0.89)	5.83 (1.09)	5.94 (1.03)	5.86 (0.94)
		Min	5.0	5.0	5.0	5.0	5.0
		Median	6.75	5.00	5.00	5.50	6.00
		Max	8.0	7.0	8.0	8.0	8.0
	Day 29	n	12	12	12	36	96
		Mean (SD)	5.75 (0.84)	5.83 (0.81)	5.71 (0.92)	5.76 (0.83)	5.82 (0.91)
		Min	5.0	5.0	5.0	5.0	5.0
		Median	5.50	6.00	5.00	5.50	5.50
		Max	7.0	7.0	7.0	7.0	8.0
	Day 50	n	10	11	12	33	92
		Mean (SD)	5.20 (0.63)	5.91 (0.92)	5.46 (0.72)	5.53 (0.80)	5.73 (0.91)
		Min	5.0	5.0	5.0	5.0	5.0
		Median	5.00	6.00	5.00	5.00	5.00
		Max	7.0	7.0	7.0	7.0	8.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.3-3: Laboratory: Descriptive statistics, continuous (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Specific Gravity	Day -30 to 0	n	12	12	12	36	96
		Mean (SD)	1.0104 (0.0075)	1.0108 (0.0073)	1.0138 (0.0074)	1.0117 (0.0074)	1.0118 (0.0071)
		Min	1.005	1.000	1.005	1.000	1.000
		Median	1.0050	1.0100	1.0125	1.0100	1.0100
		Max	1.025	1.020	1.025	1.025	1.025
	Day 1	n	12	12	12	36	96
		Mean (SD)	1.0138 (0.0057)	1.0117 (0.0078)	1.0142 (0.0073)	1.0132 (0.0069)	1.0130 (0.0067)
		Min	1.005	1.005	1.005	1.005	1.000
		Median	1.0150	1.0075	1.0125	1.0150	1.0150
		Max	1.025	1.025	1.030	1.030	1.030
	Day 2	n	12	12	12	36	96
		Mean (SD)	1.0142 (0.0060)	1.0088 (0.0043)	1.0129 (0.0062)	1.0119 (0.0059)	1.0133 (0.0059)
		Min	1.005	1.005	1.005	1.005	1.000
		Median	1.0150	1.0075	1.0125	1.0100	1.0150
		Max	1.020	1.015	1.020	1.020	1.025

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.3-3: Laboratory: Descriptive statistics, continuous (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Specific Gravity	Day 8	n	12	12	12	36	96
		Mean (SD)	1.0096 (0.0058)	1.0117 (0.0049)	1.0154 (0.0084)	1.0122 (0.0068)	1.0131 (0.0067)
		Min	1.000	1.005	1.005	1.000	1.000
		Median	1.0100	1.0125	1.0150	1.0125	1.0150
		Max	1.020	1.020	1.030	1.030	1.030
	Day 29	n	12	12	12	36	96
		Mean (SD)	1.0138 (0.0053)	1.0129 (0.0054)	1.0150 (0.0071)	1.0139 (0.0059)	1.0143 (0.0066)
		Min	1.005	1.005	1.005	1.005	1.000
		Median	1.0150	1.0100	1.0150	1.0150	1.0150
		Max	1.020	1.025	1.025	1.025	1.030
	Day 50	n	10	11	12	33	92
		Mean (SD)	1.0160 (0.0074)	1.0114 (0.0078)	1.0171 (0.0062)	1.0148 (0.0073)	1.0136 (0.0072)
		Min	1.005	1.000	1.010	1.000	1.000
		Median	1.0175	1.0100	1.0150	1.0150	1.0150
		Max	1.025	1.025	1.030	1.030	1.030

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Bacteria [/HPF]	Day -30 to 0	(+)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		+	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
		++	2 (17)	2 (17)	0 (0)	3 (25)	0 (0)	7 (12)
		+++	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	3 (5)
		massive	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
		negative	0 (0)	0 (0)	1 (8)	3 (25)	0 (0)	4 (7)
		not detectable	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 1	+	0 (0)	0 (0)	2 (17)	1 (8)	0 (0)	3 (5)
		++	1 (8)	0 (0)	1 (8)	2 (17)	0 (0)	4 (7)
		+++	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	2 (3)
		massive	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		negative	0 (0)	0 (0)	0 (0)	4 (33)	0 (0)	4 (7)
		not detectable	0 (0)	2 (17)	1 (8)	0 (0)	0 (0)	3 (5)
	Day 2	(+)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		+	1 (8)	1 (8)	0 (0)	1 (8)	0 (0)	3 (5)
		+++	1 (8)	1 (8)	0 (0)	1 (8)	3 (25)	6 (10)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Bacteria [/HPF]	Day 2	massive	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (3)
		negative	0 (0)	1 (8)	1 (8)	1 (8)	0 (0)	3 (5)
		not detectable	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (3)
	Day 8	(+)	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	3 (5)
		+	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
		++	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		+++	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	3 (5)
		massive	0 (0)	2 (17)	1 (8)	0 (0)	0 (0)	3 (5)
		negative	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)
		not detectable	1 (8)	0 (0)	1 (8)	1 (8)	0 (0)	3 (5)
	Day 29	+	1 (8)	1 (8)	1 (8)	0 (0)	0 (0)	3 (5)
		++	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		+++	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
		massive	0 (0)	0 (0)	2 (17)	2 (17)	0 (0)	4 (7)
		negative	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	3 (5)
		not detectable	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	4 (7)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 2 of 40)

Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Bacteria [/HPF]	Day 50	(+)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		++	0 (0)	0 (0)	0 (0)	3 (25)	0 (0)	3 (5)
		+++	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
		massive	0 (0)	4 (33)	0 (0)	0 (0)	0 (0)	4 (7)
		negative	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	2 (3)
		not detectable	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (3)
Bilirubin (Urine) [µmol/L]	Day -30 to 0	negative	12 (100)	11 (92)	10 (83)	12 (100)	9 (75)	54 (90)
		17.0	0 (0)	1 (8)	2 (17)	0 (0)	3 (25)	6 (10)
	Day 1	negative	12 (100)	10 (83)	12 (100)	11 (92)	11 (92)	56 (93)
		17.0	0 (0)	2 (17)	0 (0)	1 (8)	1 (8)	4 (7)
	Day 2	negative	12 (100)	11 (92)	10 (83)	12 (100)	12 (100)	57 (95)
		17.0	0 (0)	1 (8)	2 (17)	0 (0)	0 (0)	3 (5)
	Day 8	negative	11 (92)	12 (100)	9 (75)	11 (92)	11 (92)	54 (90)
		17.0	1 (8)	0 (0)	3 (25)	1 (8)	1 (8)	6 (10)
	Day 29	negative	12 (100)	12 (100)	7 (58)	12 (100)	10 (83)	53 (88)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 3 of 40)

Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Bilirubin (Urine) [µmol/L]	Day 29	17.0	0 (0)	0 (0)	5 (42)	0 (0)	2 (17)	7 (12)
	Day 50	negative	11 (92)	11 (92)	10 (83)	12 (100)	9 (75)	53 (88)
		17.0	0 (0)	1 (8)	2 (17)	0 (0)	3 (25)	6 (10)
Casts [/HPF]	Day -30 to 0	negative	2 (17)	5 (42)	3 (25)	7 (58)	1 (8)	18 (30)
		not detectable	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 1	negative	2 (17)	2 (17)	3 (25)	7 (58)	0 (0)	14 (23)
		not detectable	0 (0)	2 (17)	1 (8)	0 (0)	0 (0)	3 (5)
	Day 2	negative	2 (17)	3 (25)	2 (17)	4 (33)	3 (25)	14 (23)
		not detectable	0 (0)	1 (8)	1 (8)	1 (8)	0 (0)	3 (5)
	Day 8	negative	2 (17)	1 (8)	3 (25)	3 (25)	2 (17)	11 (18)
		not detectable	1 (8)	2 (17)	1 (8)	1 (8)	0 (0)	5 (8)
	Day 29	negative	1 (8)	2 (17)	4 (33)	2 (17)	2 (17)	11 (18)
		not detectable	1 (8)	1 (8)	1 (8)	2 (17)	1 (8)	6 (10)
	Day 50	negative	1 (8)	3 (25)	0 (0)	4 (33)	1 (8)	9 (15)
		not detectable	0 (0)	3 (25)	1 (8)	0 (0)	0 (0)	4 (7)
Crystals [/HPF]	Day -30 to 0	negative	2 (17)	3 (25)	3 (25)	6 (50)	0 (0)	14 (23)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Crystals [/HPF]	Day -30 to 0	positive	0 (0)	2 (17)	1 (8)	1 (8)	2 (17)	6 (10)
	Day 1	negative	2 (17)	1 (8)	2 (17)	5 (42)	0 (0)	10 (17)
		positive	0 (0)	2 (17)	2 (17)	2 (17)	0 (0)	6 (10)
		not detectable	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
	Day 2	negative	1 (8)	3 (25)	2 (17)	4 (33)	3 (25)	13 (22)
		positive	1 (8)	0 (0)	1 (8)	1 (8)	0 (0)	3 (5)
		not detectable	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
	Day 8	negative	2 (17)	1 (8)	2 (17)	3 (25)	2 (17)	10 (17)
		positive	1 (8)	0 (0)	2 (17)	1 (8)	0 (0)	4 (7)
		not detectable	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
	Day 29	negative	1 (8)	2 (17)	3 (25)	1 (8)	1 (8)	8 (13)
		positive	1 (8)	1 (8)	2 (17)	1 (8)	2 (17)	7 (12)
		not detectable	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (3)
	Day 50	negative	0 (0)	2 (17)	0 (0)	2 (17)	1 (8)	5 (8)
		positive	1 (8)	2 (17)	1 (8)	2 (17)	0 (0)	6 (10)
		not detectable	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Epithelial Cells [/HPF]	Day -30 to 0	massive	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		negative	0 (0)	2 (17)	1 (8)	0 (0)	0 (0)	3 (5)
		0-2	0 (0)	0 (0)	2 (17)	1 (8)	0 (0)	3 (5)
		3-6	0 (0)	3 (25)	0 (0)	4 (33)	1 (8)	8 (13)
		7-10	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	2 (3)
		11-20	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
		not detectable	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 1	negative	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		0-2	0 (0)	2 (17)	0 (0)	6 (50)	0 (0)	8 (13)
		3-6	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	3 (5)
		7-10	0 (0)	1 (8)	1 (8)	1 (8)	0 (0)	3 (5)
		11-20	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
		not detectable	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (3)
	Day 2	negative	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
		0-2	1 (8)	1 (8)	1 (8)	3 (25)	2 (17)	8 (13)
		3-6	1 (8)	1 (8)	0 (0)	1 (8)	0 (0)	3 (5)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Epithelial Cells [/HPF]	Day 2	11-20	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		not detectable	0 (0)	1 (8)	1 (8)	1 (8)	0 (0)	3 (5)
	Day 8	massive	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (3)
		negative	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
		0-2	0 (0)	0 (0)	1 (8)	2 (17)	1 (8)	4 (7)
		3-6	1 (8)	1 (8)	1 (8)	0 (0)	0 (0)	3 (5)
		7-10	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		11-20	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
		not detectable	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	4 (7)
	Day 29	massive	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
		negative	0 (0)	0 (0)	2 (17)	0 (0)	0 (0)	2 (3)
		0-2	0 (0)	1 (8)	0 (0)	1 (8)	2 (17)	4 (7)
		3-6	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (3)
		7-10	1 (8)	1 (8)	1 (8)	0 (0)	0 (0)	3 (5)
		not detectable	1 (8)	1 (8)	1 (8)	2 (17)	0 (0)	5 (8)
	Day 50	negative	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	3 (5)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Epithelial Cells [/HPF]	Day 50	0-2	1 (8)	0 (0)	0 (0)	2 (17)	0 (0)	3 (5)
		3-6	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
		7-10	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		11-20	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		not detectable	0 (0)	3 (25)	1 (8)	0 (0)	0 (0)	4 (7)
Erythrocytes (Urine) [/HPF]	Day -30 to 0	negative	1 (8)	2 (17)	1 (8)	2 (17)	0 (0)	6 (10)
		0-2	0 (0)	2 (17)	2 (17)	5 (42)	1 (8)	10 (17)
		3-6	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	2 (3)
		not detectable	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 1	massive	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		negative	1 (8)	0 (0)	0 (0)	5 (42)	0 (0)	6 (10)
		0-2	1 (8)	1 (8)	0 (0)	1 (8)	0 (0)	3 (5)
		3-6	0 (0)	1 (8)	2 (17)	1 (8)	0 (0)	4 (7)
		7-10	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
		not detectable	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (3)
	Day 2	massive	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 8 of 40)

Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Erythrocytes (Urine) [/HPF]	Day 2	negative	0 (0)	0 (0)	1 (8)	2 (17)	1 (8)	4 (7)
		0-2	0 (0)	3 (25)	1 (8)	0 (0)	1 (8)	5 (8)
		3-6	2 (17)	0 (0)	0 (0)	2 (17)	1 (8)	5 (8)
		not detectable	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (3)
	Day 8	negative	2 (17)	0 (0)	0 (0)	2 (17)	0 (0)	4 (7)
		0-2	0 (0)	1 (8)	3 (25)	0 (0)	2 (17)	6 (10)
		3-6	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		11-20	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		not detectable	1 (8)	2 (17)	1 (8)	1 (8)	0 (0)	5 (8)
	Day 29	negative	1 (8)	1 (8)	2 (17)	1 (8)	0 (0)	5 (8)
		0-2	0 (0)	1 (8)	2 (17)	0 (0)	0 (0)	3 (5)
		3-6	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	2 (3)
		21-50	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		not detectable	1 (8)	1 (8)	1 (8)	2 (17)	1 (8)	6 (10)
	Day 50	negative	0 (0)	3 (25)	0 (0)	2 (17)	1 (8)	6 (10)
		0-2	1 (8)	0 (0)	0 (0)	2 (17)	0 (0)	3 (5)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Erythrocytes (Urine) [/HPF]	Day 50	3-6	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		7-10	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		11-20	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		not detectable	0 (0)	3 (25)	1 (8)	0 (0)	0 (0)	4 (7)
Glucose (Urine)	Day -30 to 0	negative	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 1	negative	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 2	negative	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 8	negative	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 29	negative	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 50	negative	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	59 (98)
Hemoglobin (Urine) [10^6/L]	Day -30 to 0	negative	12 (100)	11 (92)	11 (92)	11 (92)	11 (92)	56 (93)
		10	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
		25	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	2 (3)
	Day 1	negative	11 (92)	9 (75)	8 (67)	7 (58)	12 (100)	47 (78)
		10	0 (0)	1 (8)	1 (8)	2 (17)	0 (0)	4 (7)
		25	0 (0)	0 (0)	1 (8)	2 (17)	0 (0)	3 (5)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Hemoglobin (Urine) [10^6/L]	Day 1	50	0 (0)	1 (8)	1 (8)	1 (8)	0 (0)	3 (5)
		250	1 (8)	1 (8)	1 (8)	0 (0)	0 (0)	3 (5)
	Day 2	negative	11 (92)	10 (83)	10 (83)	7 (58)	10 (83)	48 (80)
		10	0 (0)	0 (0)	1 (8)	2 (17)	1 (8)	4 (7)
		25	0 (0)	1 (8)	0 (0)	2 (17)	1 (8)	4 (7)
		50	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		150	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		250	1 (8)	1 (8)	1 (8)	0 (0)	0 (0)	3 (5)
	Day 8	negative	10 (83)	11 (92)	9 (75)	10 (83)	11 (92)	51 (85)
		10	1 (8)	1 (8)	2 (17)	1 (8)	0 (0)	5 (8)
		25	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (3)
		50	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		150	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		250	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)
	Day 29	negative	12 (100)	9 (75)	9 (75)	9 (75)	9 (75)	48 (80)
		10	0 (0)	1 (8)	2 (17)	1 (8)	3 (25)	7 (12)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Hemoglobin (Urine) [10^6/L]	Day 29	25	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
		50	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		150	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		250	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	2 (3)
	Day 50	negative	10 (83)	9 (75)	12 (100)	11 (92)	12 (100)	54 (90)
		10	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	2 (3)
		25	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
		50	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
Ketones [mmol/L]	Day -30 to 0	negative	12 (100)	12 (100)	12 (100)	11 (92)	10 (83)	57 (95)
		0.5	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)
		1.5	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
	Day 1	negative	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	58 (97)
		0.5	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		1.5	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
	Day 2	negative	12 (100)	11 (92)	11 (92)	11 (92)	12 (100)	57 (95)
		0.5	0 (0)	1 (8)	1 (8)	1 (8)	0 (0)	3 (5)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 12 of 40)

Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Ketones [mmol/L]	Day 8	negative	11 (92)	11 (92)	11 (92)	11 (92)	12 (100)	56 (93)
		0.5	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	4 (7)
		5.0	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 29	negative	11 (92)	12 (100)	7 (58)	12 (100)	11 (92)	53 (88)
		0.5	1 (8)	0 (0)	5 (42)	0 (0)	1 (8)	7 (12)
	Day 50	negative	9 (75)	11 (92)	12 (100)	10 (83)	11 (92)	53 (88)
		0.5	2 (17)	1 (8)	0 (0)	1 (8)	1 (8)	5 (8)
		15.0	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
Leukocytes (Urine - Dipstick) [10^6/L]	Day -30 to 0	negative	10 (83)	9 (75)	10 (83)	7 (58)	10 (83)	46 (77)
		25	2 (17)	1 (8)	1 (8)	3 (25)	2 (17)	9 (15)
		100	0 (0)	2 (17)	1 (8)	1 (8)	0 (0)	4 (7)
		500	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
	Day 1	negative	11 (92)	9 (75)	11 (92)	9 (75)	12 (100)	52 (87)
		25	1 (8)	0 (0)	1 (8)	2 (17)	0 (0)	4 (7)
		100	0 (0)	2 (17)	0 (0)	1 (8)	0 (0)	3 (5)
		500	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 13 of 40)

Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Leukocytes (Urine - Dipstick) [10^6/L]	Day 2	negative	11 (92)	9 (75)	11 (92)	10 (83)	10 (83)	51 (85)
		25	1 (8)	0 (0)	1 (8)	0 (0)	2 (17)	4 (7)
		100	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
		500	0 (0)	1 (8)	0 (0)	2 (17)	0 (0)	3 (5)
	Day 8	negative	12 (100)	10 (83)	9 (75)	8 (67)	10 (83)	49 (82)
		25	0 (0)	1 (8)	1 (8)	2 (17)	1 (8)	5 (8)
		100	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		500	0 (0)	1 (8)	2 (17)	1 (8)	1 (8)	5 (8)
	Day 29	negative	11 (92)	10 (83)	9 (75)	9 (75)	11 (92)	50 (83)
		25	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	3 (5)
		100	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	2 (3)
		500	0 (0)	1 (8)	2 (17)	2 (17)	0 (0)	5 (8)
	Day 50	negative	10 (83)	8 (67)	11 (92)	9 (75)	11 (92)	49 (82)
		25	1 (8)	3 (25)	0 (0)	2 (17)	0 (0)	6 (10)
		100	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (3)
		500	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 14 of 40)

Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Leukocytes (Urine - Microscopy) [/HPF]	Day -30 to 0	negative	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (3)
		0-2	1 (8)	1 (8)	2 (17)	3 (25)	0 (0)	7 (12)
		3-6	1 (8)	2 (17)	0 (0)	2 (17)	0 (0)	5 (8)
		7-10	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	3 (5)
		21-50	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		not detectable	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 1	negative	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		0-2	2 (17)	2 (17)	2 (17)	5 (42)	0 (0)	11 (18)
		3-6	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (3)
		7-10	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		21-50	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		not detectable	0 (0)	2 (17)	1 (8)	0 (0)	0 (0)	3 (5)
	Day 2	negative	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	3 (5)
		0-2	1 (8)	0 (0)	1 (8)	2 (17)	2 (17)	6 (10)
		3-6	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	2 (3)
		7-10	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Leukocytes (Urine - Microscopy) [/HPF]	Day 2	11-20	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		21-50	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		not detectable	0 (0)	1 (8)	1 (8)	1 (8)	0 (0)	3 (5)
	Day 8	negative	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		0-2	2 (17)	0 (0)	1 (8)	1 (8)	0 (0)	4 (7)
		3-6	0 (0)	1 (8)	0 (0)	1 (8)	2 (17)	4 (7)
		7-10	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
		11-20	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		21-50	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
		not detectable	1 (8)	2 (17)	1 (8)	1 (8)	0 (0)	5 (8)
	Day 29	massive	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		negative	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		0-2	1 (8)	1 (8)	2 (17)	1 (8)	2 (17)	7 (12)
		3-6	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
		7-10	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		11-20	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Leukocytes (Urine - Microscopy) [/HPF]	Day 29	21-50	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
		not detectable	1 (8)	1 (8)	1 (8)	1 (8)	1 (8)	5 (8)
	Day 50	negative	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		0-2	1 (8)	2 (17)	0 (0)	3 (25)	0 (0)	6 (10)
		3-6	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (3)
		7-10	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		21-50	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		not detectable	0 (0)	3 (25)	1 (8)	0 (0)	0 (0)	4 (7)
Nitrite	Day -30 to 0	negative	12 (100)	11 (92)	12 (100)	12 (100)	11 (92)	58 (97)
		positive	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (3)
	Day 1	negative	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	59 (98)
		positive	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
	Day 2	negative	12 (100)	10 (83)	11 (92)	12 (100)	11 (92)	56 (93)
		positive	0 (0)	2 (17)	1 (8)	0 (0)	1 (8)	4 (7)
	Day 8	negative	12 (100)	11 (92)	12 (100)	12 (100)	11 (92)	58 (97)
		positive	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (3)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 17 of 40)

Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Nitrite	Day 29	negative	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	59 (98)
		positive	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
	Day 50	negative	11 (92)	9 (75)	12 (100)	12 (100)	11 (92)	55 (92)
		positive	0 (0)	3 (25)	0 (0)	0 (0)	1 (8)	4 (7)
Protein [mg/L]	Day -30 to 0	negative	12 (100)	11 (92)	11 (92)	11 (92)	11 (92)	56 (93)
		250	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	4 (7)
	Day 1	negative	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	57 (95)
		250	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	2 (3)
		750	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
	Day 2	negative	12 (100)	10 (83)	11 (92)	12 (100)	12 (100)	57 (95)
		250	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		750	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		1500	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
	Day 8	negative	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
		250	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (3)
	Day 29	negative	11 (92)	12 (100)	10 (83)	10 (83)	11 (92)	54 (90)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 18 of 40)

Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Protein [mg/L]	Day 29	250	1 (8)	0 (0)	1 (8)	2 (17)	1 (8)	5 (8)
		750	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
	Day 50	negative	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
		250	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
Round Epithelial Cells [/HPF]	Day -30 to 0	negative	2 (17)	3 (25)	3 (25)	7 (58)	1 (8)	16 (27)
		0-2	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
		not detectable	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 1	negative	2 (17)	1 (8)	3 (25)	4 (33)	0 (0)	10 (17)
		0-2	0 (0)	1 (8)	0 (0)	3 (25)	0 (0)	4 (7)
		not detectable	0 (0)	2 (17)	1 (8)	0 (0)	0 (0)	3 (5)
	Day 2	negative	1 (8)	2 (17)	2 (17)	2 (17)	3 (25)	10 (17)
		0-2	1 (8)	1 (8)	0 (0)	2 (17)	0 (0)	4 (7)
		not detectable	0 (0)	1 (8)	1 (8)	1 (8)	0 (0)	3 (5)
	Day 8	negative	2 (17)	1 (8)	3 (25)	3 (25)	0 (0)	9 (15)
		0-2	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	2 (3)
		not detectable	1 (8)	2 (17)	1 (8)	1 (8)	0 (0)	5 (8)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Round Epithelial Cells [/HPF]	Day 29	negative	1 (8)	2 (17)	3 (25)	2 (17)	1 (8)	9 (15)
		0-2	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	3 (5)
		not detectable	1 (8)	1 (8)	1 (8)	2 (17)	0 (0)	5 (8)
	Day 50	negative	1 (8)	3 (25)	0 (0)	4 (33)	1 (8)	9 (15)
		0-2	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		not detectable	0 (0)	3 (25)	1 (8)	0 (0)	0 (0)	4 (7)
Urobilinogen [µmol/L]	Day -30 to 0	normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 1	normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 2	normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 8	normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 29	normal	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	59 (98)
		17	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
	Day 50	normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	59 (98)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 20 of 40)

Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Bacteria [/HPF]	Day -30 to 0	(+)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		+	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		++	0 (0)	2 (17)	0 (0)	2 (6)	9 (9)
		+++	0 (0)	1 (8)	0 (0)	1 (3)	4 (4)
		massive	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
		negative	1 (8)	2 (17)	4 (33)	7 (19)	11 (11)
		not detectable	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)
	Day 1	+	1 (8)	0 (0)	0 (0)	1 (3)	4 (4)
		++	0 (0)	0 (0)	1 (8)	1 (3)	5 (5)
		+++	0 (0)	1 (8)	1 (8)	2 (6)	4 (4)
		massive	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		negative	4 (33)	1 (8)	5 (42)	10 (28)	14 (15)
		not detectable	1 (8)	1 (8)	1 (8)	3 (8)	6 (6)
	Day 2	(+)	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
		+	1 (8)	1 (8)	1 (8)	3 (8)	6 (6)
		+++	0 (0)	0 (0)	1 (8)	1 (3)	7 (7)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Bacteria [/HPF]	Day 2	massive	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
		negative	2 (17)	1 (8)	4 (33)	7 (19)	10 (10)
		not detectable	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
	Day 8	(+)	0 (0)	1 (8)	0 (0)	1 (3)	4 (4)
		+	1 (8)	0 (0)	1 (8)	2 (6)	3 (3)
		++	0 (0)	1 (8)	1 (8)	2 (6)	3 (3)
		+++	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
		massive	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
		negative	2 (17)	4 (33)	4 (33)	10 (28)	12 (13)
		not detectable	0 (0)	0 (0)	2 (17)	2 (6)	5 (5)
	Day 29	+	0 (0)	2 (17)	0 (0)	2 (6)	5 (5)
		++	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		+++	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		massive	0 (0)	0 (0)	1 (8)	1 (3)	5 (5)
		negative	1 (8)	3 (25)	5 (42)	9 (25)	12 (13)
		not detectable	1 (8)	0 (0)	2 (17)	3 (8)	7 (7)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 22 of 40)

Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Bacteria [/HPF]	Day 50	(+)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		+	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
		++	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		+++	0 (0)	1 (8)	1 (8)	2 (6)	3 (3)
		massive	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
		negative	3 (25)	3 (25)	4 (33)	10 (28)	12 (13)
		not detectable	1 (8)	1 (8)	3 (25)	5 (14)	7 (7)
Bilirubin (Urine) [µmol/L]	Day -30 to 0	negative	11 (92)	11 (92)	11 (92)	33 (92)	87 (91)
		17.0	1 (8)	1 (8)	1 (8)	3 (8)	9 (9)
	Day 1	negative	11 (92)	12 (100)	11 (92)	34 (94)	90 (94)
		17.0	1 (8)	0 (0)	1 (8)	2 (6)	6 (6)
	Day 2	negative	12 (100)	12 (100)	11 (92)	35 (97)	92 (96)
		17.0	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
	Day 8	negative	12 (100)	12 (100)	11 (92)	35 (97)	89 (93)
		17.0	0 (0)	0 (0)	1 (8)	1 (3)	7 (7)
	Day 29	negative	12 (100)	12 (100)	12 (100)	36 (100)	89 (93)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 23 of 40)

Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Bilirubin (Urine) [µmol/L]	Day 29	17.0	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
	Day 50	negative	9 (75)	10 (83)	10 (83)	29 (81)	82 (85)
		17.0	1 (8)	1 (8)	2 (17)	4 (11)	10 (10)
Casts [/HPF]	Day -30 to 0	negative	1 (8)	5 (42)	5 (42)	11 (31)	29 (30)
		not detectable	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)
	Day 1	negative	5 (42)	2 (17)	8 (67)	15 (42)	29 (30)
		not detectable	1 (8)	1 (8)	1 (8)	3 (8)	6 (6)
	Day 2	negative	3 (25)	4 (33)	6 (50)	13 (36)	27 (28)
		not detectable	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
	Day 8	negative	3 (25)	6 (50)	8 (67)	17 (47)	28 (29)
		not detectable	0 (0)	0 (0)	2 (17)	2 (6)	7 (7)
	Day 29	negative	1 (8)	5 (42)	6 (50)	12 (33)	23 (24)
		not detectable	1 (8)	0 (0)	3 (25)	4 (11)	10 (10)
	Day 50	negative	3 (25)	5 (42)	5 (42)	13 (36)	22 (23)
		not detectable	1 (8)	1 (8)	3 (25)	5 (14)	9 (9)
Crystals [/HPF]	Day -30 to 0	negative	1 (8)	3 (25)	4 (33)	8 (22)	22 (23)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 24 of 40)

Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Crystals [/HPF]	Day -30 to 0	positive	0 (0)	2 (17)	3 (25)	5 (14)	11 (11)
	Day 1	negative	4 (33)	2 (17)	6 (50)	12 (33)	22 (23)
		positive	2 (17)	1 (8)	3 (25)	6 (17)	12 (13)
		not detectable	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 2	negative	2 (17)	4 (33)	5 (42)	11 (31)	24 (25)
		positive	1 (8)	0 (0)	2 (17)	3 (8)	6 (6)
		not detectable	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 8	negative	3 (25)	5 (42)	7 (58)	15 (42)	25 (26)
		positive	0 (0)	1 (8)	3 (25)	4 (11)	8 (8)
		not detectable	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 29	negative	1 (8)	4 (33)	6 (50)	11 (31)	19 (20)
		positive	1 (8)	1 (8)	2 (17)	4 (11)	11 (11)
		not detectable	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
	Day 50	negative	3 (25)	5 (42)	4 (33)	12 (33)	17 (18)
		positive	1 (8)	1 (8)	4 (33)	6 (17)	12 (13)
		not detectable	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 25 of 40)

Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Epithelial Cells [/HPF]	Day -30 to 0	massive	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		negative	1 (8)	1 (8)	1 (8)	3 (8)	6 (6)
		0-2	0 (0)	3 (25)	2 (17)	5 (14)	8 (8)
		3-6	0 (0)	1 (8)	2 (17)	3 (8)	11 (11)
		7-10	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		11-20	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)
	Day 1	negative	2 (17)	1 (8)	1 (8)	4 (11)	4 (4)
		0-2	2 (17)	1 (8)	4 (33)	7 (19)	15 (16)
		3-6	1 (8)	0 (0)	2 (17)	3 (8)	6 (6)
		7-10	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		11-20	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		not detectable	1 (8)	1 (8)	1 (8)	3 (8)	5 (5)
	Day 2	negative	1 (8)	2 (17)	3 (25)	6 (17)	8 (8)
		0-2	2 (17)	2 (17)	3 (25)	7 (19)	15 (16)
		3-6	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Epithelial Cells [/HPF]	Day 2	11-20	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
	Day 8	massive	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		negative	2 (17)	0 (0)	2 (17)	4 (11)	5 (5)
		0-2	0 (0)	4 (33)	5 (42)	9 (25)	13 (14)
		3-6	1 (8)	2 (17)	0 (0)	3 (8)	6 (6)
		7-10	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		11-20	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		not detectable	0 (0)	0 (0)	2 (17)	2 (6)	6 (6)
	Day 29	massive	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		negative	1 (8)	3 (25)	2 (17)	6 (17)	8 (8)
		0-2	0 (0)	2 (17)	3 (25)	5 (14)	9 (9)
		3-6	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
		7-10	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		not detectable	1 (8)	0 (0)	3 (25)	4 (11)	9 (9)
	Day 50	negative	1 (8)	2 (17)	1 (8)	4 (11)	7 (7)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Epithelial Cells [/HPF]	Day 50	0-2	2 (17)	2 (17)	3 (25)	7 (19)	10 (10)
		3-6	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
		7-10	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		11-20	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
		not detectable	1 (8)	1 (8)	3 (25)	5 (14)	9 (9)
Erythrocytes (Urine) [/HPF]	Day -30 to 0	negative	0 (0)	4 (33)	1 (8)	5 (14)	11 (11)
		0-2	0 (0)	1 (8)	4 (33)	5 (14)	15 (16)
		3-6	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
		not detectable	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)
	Day 1	massive	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		negative	2 (17)	2 (17)	1 (8)	5 (14)	11 (11)
		0-2	2 (17)	0 (0)	3 (25)	5 (14)	8 (8)
		3-6	1 (8)	0 (0)	4 (33)	5 (14)	9 (9)
		7-10	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	1 (8)	1 (8)	1 (8)	3 (8)	5 (5)
	Day 2	massive	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Erythrocytes (Urine) [/HPF]	Day 2	negative	1 (8)	3 (25)	2 (17)	6 (17)	10 (10)
		0-2	2 (17)	1 (8)	4 (33)	7 (19)	12 (13)
		3-6	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
		not detectable	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
	Day 8	negative	1 (8)	2 (17)	0 (0)	3 (8)	7 (7)
		0-2	2 (17)	1 (8)	5 (42)	8 (22)	14 (15)
		3-6	0 (0)	2 (17)	3 (25)	5 (14)	5 (5)
		11-20	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
		not detectable	0 (0)	0 (0)	2 (17)	2 (6)	7 (7)
	Day 29	negative	0 (0)	3 (25)	0 (0)	3 (8)	8 (8)
		0-2	0 (0)	2 (17)	5 (42)	7 (19)	10 (10)
		3-6	1 (8)	0 (0)	1 (8)	2 (6)	4 (4)
		21-50	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	1 (8)	0 (0)	3 (25)	4 (11)	10 (10)
	Day 50	negative	0 (0)	3 (25)	1 (8)	4 (11)	10 (10)
		0-2	2 (17)	1 (8)	3 (25)	6 (17)	9 (9)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 29 of 40)

Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Erythrocytes (Urine) [/HPF]	Day 50	3-6	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
		7-10	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
		11-20	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
		not detectable	1 (8)	1 (8)	3 (25)	5 (14)	9 (9)
Glucose (Urine)	Day -30 to 0	negative	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 1	negative	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 2	negative	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 8	negative	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 29	negative	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 50	negative	10 (83)	11 (92)	12 (100)	33 (92)	92 (96)
Hemoglobin (Urine) [10^6/L]	Day -30 to 0	negative	11 (92)	11 (92)	6 (50)	28 (78)	84 (88)
		10	0 (0)	0 (0)	4 (33)	4 (11)	6 (6)
		25	1 (8)	1 (8)	2 (17)	4 (11)	6 (6)
	Day 1	negative	8 (67)	11 (92)	3 (25)	22 (61)	69 (72)
		10	3 (25)	0 (0)	4 (33)	7 (19)	11 (11)
		25	1 (8)	0 (0)	3 (25)	4 (11)	7 (7)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Hemoglobin (Urine) [10^6/L]	Day 1	50	0 (0)	0 (0)	2 (17)	2 (6)	5 (5)
		250	0 (0)	1 (8)	0 (0)	1 (3)	4 (4)
	Day 2	negative	9 (75)	9 (75)	5 (42)	23 (64)	71 (74)
		10	2 (17)	2 (17)	3 (25)	7 (19)	11 (11)
		25	1 (8)	1 (8)	3 (25)	5 (14)	9 (9)
		50	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
		150	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		250	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Day 8	negative	10 (83)	9 (75)	4 (33)	23 (64)	74 (77)
		10	2 (17)	1 (8)	3 (25)	6 (17)	11 (11)
		25	0 (0)	1 (8)	4 (33)	5 (14)	7 (7)
		50	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
		150	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
		250	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 29	negative	11 (92)	8 (67)	6 (50)	25 (69)	73 (76)
		10	0 (0)	0 (0)	4 (33)	4 (11)	11 (11)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 31 of 40)

Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Hemoglobin (Urine) [10^6/L]	Day 29	25	0 (0)	3 (25)	2 (17)	5 (14)	6 (6)
		50	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
		150	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
		250	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 50	negative	7 (58)	6 (50)	4 (33)	17 (47)	71 (74)
		10	2 (17)	2 (17)	5 (42)	9 (25)	11 (11)
		25	1 (8)	2 (17)	2 (17)	5 (14)	7 (7)
		50	0 (0)	1 (8)	1 (8)	2 (6)	3 (3)
Ketones [mmol/L]	Day -30 to 0	negative	12 (100)	12 (100)	12 (100)	36 (100)	93 (97)
		0.5	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		1.5	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 1	negative	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
		0.5	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		1.5	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 2	negative	12 (100)	12 (100)	11 (92)	35 (97)	92 (96)
		0.5	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 32 of 40)

Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Ketones [mmol/L]	Day 8	negative	12 (100)	12 (100)	11 (92)	35 (97)	91 (95)
		0.5	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
		5.0	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
	Day 29	negative	12 (100)	12 (100)	12 (100)	36 (100)	89 (93)
		0.5	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
	Day 50	negative	10 (83)	11 (92)	12 (100)	33 (92)	86 (90)
		0.5	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
		15.0	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Leukocytes (Urine - Dipstick) [10^6/L]	Day -30 to 0	negative	12 (100)	9 (75)	9 (75)	30 (83)	76 (79)
		25	0 (0)	1 (8)	0 (0)	1 (3)	10 (10)
		100	0 (0)	1 (8)	1 (8)	2 (6)	6 (6)
		500	0 (0)	1 (8)	2 (17)	3 (8)	4 (4)
	Day 1	negative	9 (75)	9 (75)	8 (67)	26 (72)	78 (81)
		25	0 (0)	1 (8)	1 (8)	2 (6)	6 (6)
		100	1 (8)	0 (0)	2 (17)	3 (8)	6 (6)
		500	2 (17)	2 (17)	1 (8)	5 (14)	6 (6)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 33 of 40)

Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Leukocytes (Urine - Dipstick) [10^6/L]	Day 2	negative	11 (92)	10 (83)	9 (75)	30 (83)	81 (84)
		25	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
		100	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
		500	1 (8)	2 (17)	2 (17)	5 (14)	8 (8)
	Day 8	negative	10 (83)	9 (75)	5 (42)	24 (67)	73 (76)
		25	1 (8)	1 (8)	5 (42)	7 (19)	12 (13)
		100	0 (0)	2 (17)	1 (8)	3 (8)	4 (4)
		500	1 (8)	0 (0)	1 (8)	2 (6)	7 (7)
	Day 29	negative	11 (92)	9 (75)	5 (42)	25 (69)	75 (78)
		25	0 (0)	1 (8)	3 (25)	4 (11)	7 (7)
		100	0 (0)	1 (8)	1 (8)	2 (6)	4 (4)
		500	1 (8)	1 (8)	3 (25)	5 (14)	10 (10)
	Day 50	negative	9 (75)	8 (67)	8 (67)	25 (69)	74 (77)
		25	0 (0)	1 (8)	2 (17)	3 (8)	9 (9)
		100	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)
		500	1 (8)	2 (17)	0 (0)	3 (8)	5 (5)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Leukocytes (Urine - Microscopy) [/HPF]	Day -30 to 0	negative	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
		0-2	1 (8)	3 (25)	1 (8)	5 (14)	12 (13)
		3-6	0 (0)	0 (0)	2 (17)	2 (6)	7 (7)
		7-10	0 (0)	2 (17)	0 (0)	2 (6)	5 (5)
		21-50	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		not detectable	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)
	Day 1	negative	2 (17)	0 (0)	1 (8)	3 (8)	4 (4)
		0-2	1 (8)	1 (8)	4 (33)	6 (17)	17 (18)
		3-6	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
		7-10	2 (17)	1 (8)	0 (0)	3 (8)	3 (3)
		21-50	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
		not detectable	1 (8)	1 (8)	1 (8)	3 (8)	6 (6)
	Day 2	negative	0 (0)	1 (8)	0 (0)	1 (3)	4 (4)
		0-2	2 (17)	1 (8)	3 (25)	6 (17)	12 (13)
		3-6	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)
		7-10	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 35 of 40)

Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Leukocytes (Urine - Microscopy) [/HPF]	Day 2	11-20	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
		21-50	1 (8)	1 (8)	1 (8)	3 (8)	4 (4)
		not detectable	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
	Day 8	negative	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
		0-2	2 (17)	3 (25)	2 (17)	7 (19)	11 (11)
		3-6	1 (8)	3 (25)	2 (17)	6 (17)	10 (10)
		7-10	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		11-20	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		21-50	0 (0)	0 (0)	2 (17)	2 (6)	3 (3)
		not detectable	0 (0)	0 (0)	2 (17)	2 (6)	7 (7)
	Day 29	massive	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		negative	0 (0)	2 (17)	1 (8)	3 (8)	4 (4)
		0-2	1 (8)	1 (8)	2 (17)	4 (11)	11 (11)
		3-6	0 (0)	2 (17)	2 (17)	4 (11)	5 (5)
		7-10	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
		11-20	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 36 of 40)

Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Leukocytes (Urine - Microscopy) [/HPF]	Day 29	21-50	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		not detectable	1 (8)	0 (0)	3 (25)	4 (11)	9 (9)
	Day 50	negative	2 (17)	1 (8)	0 (0)	3 (8)	3 (3)
		0-2	1 (8)	2 (17)	3 (25)	6 (17)	12 (13)
		3-6	0 (0)	1 (8)	1 (8)	2 (6)	4 (4)
		7-10	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		21-50	0 (0)	1 (8)	1 (8)	2 (6)	2 (2)
		not detectable	1 (8)	1 (8)	3 (25)	5 (14)	9 (9)
Nitrite	Day -30 to 0	negative	12 (100)	10 (83)	11 (92)	33 (92)	91 (95)
		positive	0 (0)	2 (17)	1 (8)	3 (8)	5 (5)
	Day 1	negative	12 (100)	12 (100)	11 (92)	35 (97)	94 (98)
		positive	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
	Day 2	negative	12 (100)	12 (100)	11 (92)	35 (97)	91 (95)
		positive	0 (0)	0 (0)	1 (8)	1 (3)	5 (5)
	Day 8	negative	12 (100)	12 (100)	10 (83)	34 (94)	92 (96)
		positive	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 37 of 40)

Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Nitrite	Day 29	negative	12 (100)	12 (100)	11 (92)	35 (97)	94 (98)
		positive	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
	Day 50	negative	10 (83)	10 (83)	11 (92)	31 (86)	86 (90)
		positive	0 (0)	1 (8)	1 (8)	2 (6)	6 (6)
Protein [mg/L]	Day -30 to 0	negative	12 (100)	12 (100)	12 (100)	36 (100)	92 (96)
		250	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
	Day 1	negative	12 (100)	11 (92)	12 (100)	35 (97)	92 (96)
		250	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
		750	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 2	negative	12 (100)	12 (100)	12 (100)	36 (100)	93 (97)
		250	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		750	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		1500	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 8	negative	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
		250	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 29	negative	12 (100)	12 (100)	12 (100)	36 (100)	90 (94)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 38 of 40)

Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Protein [mg/L]	Day 29	250	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
		750	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 50	negative	9 (75)	11 (92)	12 (100)	32 (89)	90 (94)
		250	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
Round Epithelial Cells [/HPF]	Day -30 to 0	negative	1 (8)	2 (17)	2 (17)	5 (14)	21 (22)
		0-2	0 (0)	3 (25)	3 (25)	6 (17)	8 (8)
		not detectable	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)
	Day 1	negative	4 (33)	2 (17)	7 (58)	13 (36)	23 (24)
		0-2	1 (8)	0 (0)	1 (8)	2 (6)	6 (6)
		not detectable	1 (8)	1 (8)	1 (8)	3 (8)	6 (6)
	Day 2	negative	2 (17)	3 (25)	6 (50)	11 (31)	21 (22)
		0-2	1 (8)	1 (8)	0 (0)	2 (6)	6 (6)
		not detectable	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
	Day 8	negative	2 (17)	4 (33)	8 (67)	14 (39)	23 (24)
		0-2	1 (8)	2 (17)	0 (0)	3 (8)	5 (5)
		not detectable	0 (0)	0 (0)	2 (17)	2 (6)	7 (7)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-2.1.4-3: Laboratory: Descriptive statistics, categorical (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Round Epithelial Cells [/HPF]	Day 29	negative	1 (8)	3 (25)	5 (42)	9 (25)	18 (19)
		0-2	0 (0)	2 (17)	1 (8)	3 (8)	6 (6)
		not detectable	1 (8)	0 (0)	3 (25)	4 (11)	9 (9)
	Day 50	negative	3 (25)	4 (33)	5 (42)	12 (33)	21 (22)
		0-2	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
		not detectable	1 (8)	1 (8)	3 (25)	5 (14)	9 (9)
Urobilinogen [µmol/L]	Day -30 to 0	normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 1	normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 2	normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 8	normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 29	normal	12 (100)	12 (100)	12 (100)	36 (100)	95 (99)
		17	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 50	normal	10 (83)	11 (92)	12 (100)	33 (92)	92 (96)

The denominator for the percentage calculation is N.
N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_LB_2_1.sas (Page 40 of 40)

14.3.2-2.5 Abnormal and clinically significant values per visit

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Basophils (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	0 (0)	1 (8)	3 (5)
		Normal	11 (92)	9 (75)	11 (92)	12 (100)	11 (92)	54 (90)
	Day 1	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	3 (5)
		Normal	11 (92)	11 (92)	12 (100)	11 (92)	10 (83)	55 (92)
	Day 2	Abnormal (not CS)	2 (17)	0 (0)	0 (0)	0 (0)	1 (8)	3 (5)
		Normal	10 (83)	12 (100)	12 (100)	12 (100)	11 (92)	57 (95)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (3)
		Normal	11 (92)	12 (100)	11 (92)	12 (100)	10 (83)	56 (93)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
		Normal	11 (92)	11 (92)	11 (92)	11 (92)	9 (75)	53 (88)
		Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
		Normal	9 (75)	12 (100)	11 (92)	12 (100)	11 (92)	55 (92)
Basophils (Blood Smear) [10^9/L]	Day -30 to 0	Missing	0 (0)	3 (25)	0 (0)	0 (0)	0 (0)	3 (5)
	Day 1	Missing	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (3)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 1 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Basophils (Blood Smear) [10^9/L]	Day 8	Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 29	Missing	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	4 (7)
	Day 50	Missing	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (3)
Basophils/Leukocytes (Blood) [%]	Day -30 to 0	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	11 (92)	9 (75)	12 (100)	12 (100)	12 (100)	56 (93)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	3 (5)
		Normal	10 (83)	12 (100)	12 (100)	11 (92)	10 (83)	55 (92)
	Day 2	Abnormal (not CS)	4 (33)	0 (0)	0 (0)	0 (0)	0 (0)	4 (7)
		Normal	8 (67)	12 (100)	12 (100)	12 (100)	12 (100)	56 (93)
	Day 8	Abnormal (not CS)	3 (25)	0 (0)	0 (0)	0 (0)	0 (0)	3 (5)
		Normal	9 (75)	12 (100)	11 (92)	12 (100)	11 (92)	55 (92)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (3)
		Normal	10 (83)	11 (92)	11 (92)	11 (92)	9 (75)	52 (87)
		Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 50	Normal	9 (75)	12 (100)	12 (100)	12 (100)	12 (100)	57 (95)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 2 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Basophils/Leukocytes (Blood Smear) [%]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	2 (3)
		Normal	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
		Missing	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
	Day 50	Abnormal (not CS)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (3)
Eosinophils (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	12 (100)	9 (75)	12 (100)	12 (100)	12 (100)	57 (95)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	3 (5)
		Normal	11 (92)	12 (100)	11 (92)	12 (100)	9 (75)	55 (92)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 3 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Eosinophils (Blood) [10^9/L]	Day 2	Normal	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	59 (98)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	12 (100)	12 (100)	11 (92)	12 (100)	11 (92)	58 (97)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	11 (92)	11 (92)	11 (92)	11 (92)	10 (83)	54 (90)
		Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
		Normal	9 (75)	12 (100)	11 (92)	12 (100)	11 (92)	55 (92)
Eosinophils (Blood Smear) [10^9/L]	Day -30 to 0	Missing	0 (0)	3 (25)	0 (0)	0 (0)	0 (0)	3 (5)
	Day 1	Missing	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (3)
	Day 8	Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 29	Missing	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	4 (7)
	Day 50	Missing	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (3)
Eosinophils/Leukocytes (Blood) [%]	Day -30 to 0	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	3 (5)
		Normal	11 (92)	9 (75)	12 (100)	11 (92)	11 (92)	54 (90)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 4 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Eosinophils/Leukocytes (Blood) [%]	Day 1	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
		Normal	11 (92)	12 (100)	11 (92)	12 (100)	10 (83)	56 (93)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	3 (25)	4 (7)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	9 (75)	56 (93)
	Day 8	Abnormal (not CS)	3 (25)	0 (0)	1 (8)	2 (17)	1 (8)	7 (12)
		Normal	9 (75)	12 (100)	10 (83)	10 (83)	10 (83)	51 (85)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (3)
		Normal	10 (83)	11 (92)	11 (92)	11 (92)	9 (75)	52 (87)
		Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	2 (17)	3 (5)
		Normal	8 (67)	12 (100)	12 (100)	12 (100)	10 (83)	54 (90)
Eosinophils/Leukocytes (Blood Smear) [%]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
	Day 1	Normal	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (3)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 5 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Eosinophils/Leukocytes (Blood Smear) [%]	Day 8	Normal	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
	Day 29	Normal	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	3 (5)
		Missing	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
	Day 50	Normal	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (3)
Erythrocytes (Blood) [10^{12}/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		Normal	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	59 (98)
	Day 1	Abnormal (not CS)	3 (25)	2 (17)	3 (25)	2 (17)	2 (17)	12 (20)
		Normal	9 (75)	10 (83)	9 (75)	10 (83)	10 (83)	48 (80)
	Day 2	Abnormal (not CS)	0 (0)	2 (17)	3 (25)	1 (8)	1 (8)	7 (12)
		Normal	12 (100)	10 (83)	9 (75)	11 (92)	11 (92)	53 (88)
	Day 8	Abnormal (not CS)	3 (25)	2 (17)	2 (17)	2 (17)	2 (17)	11 (18)
		Normal	9 (75)	10 (83)	10 (83)	10 (83)	10 (83)	49 (82)
	Day 29	Abnormal (not CS)	0 (0)	2 (17)	1 (8)	2 (17)	2 (17)	7 (12)
		Normal	12 (100)	10 (83)	10 (83)	10 (83)	9 (75)	51 (85)
		Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 6 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Erythrocytes (Blood) [10^{12}/L]	Day 50	Abnormal (not CS)	2 (17)	3 (25)	2 (17)	1 (8)	3 (25)	11 (18)
		Normal	9 (75)	9 (75)	10 (83)	11 (92)	9 (75)	48 (80)
Hematocrit [L/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)
		Normal	12 (100)	12 (100)	12 (100)	11 (92)	11 (92)	58 (97)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		Normal	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	59 (98)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		Normal	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	59 (98)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	1 (8)	0 (0)	3 (5)
		Normal	11 (92)	12 (100)	10 (83)	11 (92)	11 (92)	55 (92)
		Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	59 (98)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 7 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Hemoglobin (Blood) [mmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	3 (5)
		Normal	12 (100)	12 (100)	11 (92)	11 (92)	11 (92)	57 (95)
	Day 1	Abnormal (not CS)	1 (8)	3 (25)	0 (0)	2 (17)	2 (17)	8 (13)
		Normal	11 (92)	9 (75)	12 (100)	10 (83)	10 (83)	52 (87)
	Day 2	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (17)	2 (17)	6 (10)
		Normal	12 (100)	11 (92)	11 (92)	10 (83)	10 (83)	54 (90)
	Day 8	Abnormal (not CS)	3 (25)	2 (17)	1 (8)	3 (25)	4 (33)	13 (22)
		Normal	9 (75)	10 (83)	11 (92)	9 (75)	8 (67)	47 (78)
	Day 29	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (17)	3 (25)	7 (12)
		Normal	12 (100)	11 (92)	10 (83)	10 (83)	8 (67)	51 (85)
		Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 50	Abnormal (not CS)	3 (25)	4 (33)	1 (8)	3 (25)	3 (25)	14 (23)
		Normal	8 (67)	8 (67)	11 (92)	9 (75)	9 (75)	45 (75)
Leukocytes (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	2 (17)	0 (0)	0 (0)	1 (8)	0 (0)	3 (5)
		Normal	10 (83)	12 (100)	12 (100)	11 (92)	12 (100)	57 (95)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 8 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Leukocytes (Blood) [10^9/L]	Day 1	Abnormal (not CS)	1 (8)	1 (8)	3 (25)	1 (8)	2 (17)	8 (13)
		Normal	11 (92)	11 (92)	9 (75)	11 (92)	10 (83)	52 (87)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	59 (98)
	Day 8	Abnormal (not CS)	1 (8)	2 (17)	1 (8)	3 (25)	1 (8)	8 (13)
		Normal	11 (92)	10 (83)	11 (92)	9 (75)	11 (92)	52 (87)
	Day 29	Abnormal (not CS)	2 (17)	3 (25)	0 (0)	4 (33)	1 (8)	10 (17)
		Normal	10 (83)	9 (75)	11 (92)	8 (67)	10 (83)	48 (80)
		Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 50	Abnormal (not CS)	3 (25)	1 (8)	1 (8)	4 (33)	1 (8)	10 (17)
		Normal	8 (67)	11 (92)	11 (92)	8 (67)	11 (92)	49 (82)
Lymphocytes (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (3)
		Normal	12 (100)	9 (75)	12 (100)	10 (83)	12 (100)	55 (92)
	Day 1	Abnormal (not CS)	0 (0)	2 (17)	1 (8)	2 (17)	0 (0)	5 (8)
		Normal	11 (92)	10 (83)	11 (92)	10 (83)	11 (92)	53 (88)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 9 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Lymphocytes (Blood) [10^9/L]	Day 2	Abnormal (not CS)	0 (0)	1 (8)	2 (17)	7 (58)	6 (50)	16 (27)
		Normal	12 (100)	11 (92)	10 (83)	5 (42)	6 (50)	44 (73)
	Day 8	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (17)	0 (0)	4 (7)
		Normal	11 (92)	11 (92)	11 (92)	10 (83)	11 (92)	54 (90)
	Day 29	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	3 (25)	0 (0)	4 (7)
		Normal	11 (92)	10 (83)	11 (92)	8 (67)	10 (83)	50 (83)
		Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 50	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	2 (17)	1 (8)	4 (7)
		Normal	9 (75)	11 (92)	12 (100)	10 (83)	11 (92)	53 (88)
Lymphocytes (Blood Smear) [10^9/L]	Day -30 to 0	Missing	0 (0)	3 (25)	0 (0)	0 (0)	0 (0)	3 (5)
	Day 1	Missing	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (3)
	Day 8	Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 29	Missing	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	4 (7)
	Day 50	Missing	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (3)
Lymphocytes/Leukocytes (Blood) [%]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 10 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Lymphocytes/Leukocytes (Blood) [%]	Day -30 to 0	Normal	12 (100)	9 (75)	12 (100)	12 (100)	12 (100)	57 (95)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	3 (5)
		Normal	11 (92)	12 (100)	12 (100)	11 (92)	9 (75)	55 (92)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (8)	4 (33)	6 (10)
		Normal	12 (100)	12 (100)	11 (92)	11 (92)	8 (67)	54 (90)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	12 (100)	12 (100)	11 (92)	12 (100)	11 (92)	58 (97)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	3 (5)
		Normal	11 (92)	11 (92)	10 (83)	10 (83)	9 (75)	51 (85)
		Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
		Normal	9 (75)	12 (100)	11 (92)	12 (100)	12 (100)	56 (93)
Lymphocytes/Leukocytes (Blood Smear) [%]	Day -30 to 0	Abnormal (not CS)	0 (0)	3 (25)	0 (0)	0 (0)	0 (0)	3 (5)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
		Normal	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 11 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Lymphocytes/Leukocytes (Blood Smear) [%]	Day 8	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
		Normal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	3 (5)
		Missing	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
	Day 50	Abnormal (not CS)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (3)
Monocytes (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		Normal	12 (100)	9 (75)	12 (100)	11 (92)	12 (100)	56 (93)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	10 (83)	12 (100)	12 (100)	12 (100)	11 (92)	57 (95)
	Day 2	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	0 (0)	2 (17)	4 (7)
		Normal	11 (92)	11 (92)	12 (100)	12 (100)	10 (83)	56 (93)
	Day 8	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	2 (3)
		Normal	11 (92)	11 (92)	11 (92)	12 (100)	11 (92)	56 (93)
	Day 29	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	11 (92)	10 (83)	11 (92)	11 (92)	10 (83)	53 (88)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 12 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Monocytes (Blood) [10^9/L]	Day 29	Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 50	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	4 (7)
		Normal	8 (67)	11 (92)	11 (92)	12 (100)	11 (92)	53 (88)
Monocytes (Blood Smear) [10^9/L]	Day -30 to 0	Missing	0 (0)	3 (25)	0 (0)	0 (0)	0 (0)	3 (5)
	Day 1	Missing	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (3)
	Day 8	Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 29	Missing	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	4 (7)
	Day 50	Missing	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (3)
Monocytes/Leukocytes (Blood) [%]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
		Normal	12 (100)	9 (75)	12 (100)	12 (100)	11 (92)	56 (93)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	2 (17)	3 (5)
		Normal	10 (83)	12 (100)	12 (100)	12 (100)	9 (75)	55 (92)
	Day 2	Abnormal (not CS)	2 (17)	0 (0)	1 (8)	0 (0)	3 (25)	6 (10)
		Normal	10 (83)	12 (100)	11 (92)	12 (100)	9 (75)	54 (90)
	Day 8	Abnormal (not CS)	2 (17)	0 (0)	0 (0)	1 (8)	0 (0)	3 (5)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 13 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Monocytes/Leukocytes (Blood) [%]	Day 8	Normal	10 (83)	12 (100)	11 (92)	11 (92)	11 (92)	55 (92)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	10 (83)	11 (92)	11 (92)	11 (92)	10 (83)	53 (88)
		Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	2 (17)	0 (0)	1 (8)	4 (7)
		Normal	8 (67)	12 (100)	10 (83)	12 (100)	11 (92)	53 (88)
Monocytes/Leukocytes (Blood Smear) [%]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
	Day 8	Normal	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 29	Normal	1 (8)	0 (0)	0 (0)	1 (8)	1 (8)	3 (5)
		Missing	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
	Day 50	Normal	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (3)
Neutrophils (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (3)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 14 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Neutrophils (Blood) [10^9/L]	Day -30 to 0	Normal	11 (92)	9 (75)	12 (100)	12 (100)	11 (92)	55 (92)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	2 (17)	1 (8)	2 (17)	6 (10)
		Normal	10 (83)	12 (100)	10 (83)	11 (92)	9 (75)	52 (87)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	2 (17)	3 (5)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	10 (83)	57 (95)
	Day 8	Abnormal (not CS)	2 (17)	0 (0)	1 (8)	3 (25)	1 (8)	7 (12)
		Normal	10 (83)	12 (100)	10 (83)	9 (75)	10 (83)	51 (85)
	Day 29	Abnormal (not CS)	2 (17)	1 (8)	2 (17)	1 (8)	2 (17)	8 (13)
		Normal	9 (75)	10 (83)	9 (75)	10 (83)	8 (67)	46 (77)
		Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 50	Abnormal (not CS)	3 (25)	0 (0)	2 (17)	2 (17)	0 (0)	7 (12)
		Normal	6 (50)	12 (100)	10 (83)	10 (83)	12 (100)	50 (83)
Neutrophils (Blood Smear) [10^9/L]	Day -30 to 0	Missing	0 (0)	3 (25)	0 (0)	0 (0)	0 (0)	3 (5)
	Day 1	Missing	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (3)
	Day 8	Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 15 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Neutrophils (Blood Smear) [10^9/L]	Day 29	Missing	1 (8)	1 (8)	0 (0)	1 (8)	1 (8)	4 (7)
	Day 50	Missing	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (3)
Neutrophils/Leukocytes (Blood) [%]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	12 (100)	9 (75)	12 (100)	12 (100)	12 (100)	57 (95)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	11 (92)	58 (97)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)
		Normal	12 (100)	12 (100)	12 (100)	11 (92)	11 (92)	58 (97)
	Day 8	Abnormal (not CS)	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (3)
		Normal	10 (83)	12 (100)	11 (92)	12 (100)	11 (92)	56 (93)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	0 (0)	1 (8)	3 (5)
		Normal	10 (83)	11 (92)	10 (83)	11 (92)	9 (75)	51 (85)
		Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	8 (67)	12 (100)	12 (100)	12 (100)	12 (100)	56 (93)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

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Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Neutrophils/Leukocytes (Blood Smear) [%]	Day -30 to 0	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
		Normal	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
		Normal	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
		Normal	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (3)
		Normal	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		Missing	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
	Day 50	Normal	2 (17)	0 (0)	0 (0)	0 (0)	0 (0)	2 (3)
Platelets [10^9/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (3)
		Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	58 (97)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	3 (25)	1 (8)	0 (0)	4 (7)
		Normal	12 (100)	12 (100)	9 (75)	11 (92)	12 (100)	56 (93)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	1 (8)	0 (0)	3 (5)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 17 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Platelets [10^9/L]	Day 2	Normal	12 (100)	12 (100)	10 (83)	11 (92)	12 (100)	57 (95)
	Day 8	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (3)
		Normal	12 (100)	11 (92)	11 (92)	12 (100)	12 (100)	58 (97)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	1 (8)	0 (0)	3 (5)
		Normal	12 (100)	12 (100)	9 (75)	11 (92)	11 (92)	55 (92)
		Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	2 (17)	0 (0)	0 (0)	3 (5)
		Normal	10 (83)	12 (100)	10 (83)	12 (100)	12 (100)	56 (93)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 18 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Basophils (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (6)	5 (5)
		Normal	12 (100)	11 (92)	11 (92)	34 (94)	88 (92)
	Day 1	Abnormal (not CS)	1 (8)	2 (17)	1 (8)	4 (11)	7 (7)
		Normal	11 (92)	10 (83)	11 (92)	32 (89)	87 (91)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	92 (96)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	91 (95)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	88 (92)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 50	Abnormal (not CS)	1 (8)	2 (17)	0 (0)	3 (8)	5 (5)
		Normal	9 (75)	9 (75)	12 (100)	30 (83)	85 (89)
Basophils (Blood Smear) [10^9/L]	Day -30 to 0	Missing	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Day 1	Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

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Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Basophils (Blood Smear) [10^9/L]	Day 8	Missing	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
	Day 29	Missing	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
	Day 50	Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Basophils/Leukocytes (Blood) [%]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	92 (96)
	Day 1	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (6)	5 (5)
		Normal	11 (92)	11 (92)	12 (100)	34 (94)	89 (93)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	92 (96)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	90 (94)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	87 (91)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 50	Normal	10 (83)	11 (92)	12 (100)	33 (92)	90 (94)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

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Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Basophils/Leukocytes (Blood Smear) [%]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
		Normal	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Eosinophils (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	92 (96)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	5 (5)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	89 (93)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

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Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Eosinophils (Blood) [10^9/L]	Day 2	Normal	11 (92)	12 (100)	12 (100)	35 (97)	94 (98)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
		Normal	10 (83)	12 (100)	12 (100)	34 (94)	92 (96)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	88 (92)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	10 (83)	11 (92)	12 (100)	33 (92)	88 (92)
Eosinophils (Blood Smear) [10^9/L]	Day -30 to 0	Missing	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Day 1	Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 8	Missing	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
	Day 29	Missing	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
	Day 50	Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Eosinophils/Leukocytes (Blood) [%]	Day -30 to 0	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	4 (4)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	89 (93)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

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Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Eosinophils/Leukocytes (Blood) [%]	Day 1	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	4 (4)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	90 (94)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	5 (5)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	91 (95)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	8 (8)
		Normal	10 (83)	12 (100)	12 (100)	34 (94)	85 (89)
	Day 29	Abnormal (not CS)	2 (17)	0 (0)	1 (8)	3 (8)	5 (5)
		Normal	10 (83)	12 (100)	11 (92)	33 (92)	85 (89)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		Normal	10 (83)	11 (92)	12 (100)	33 (92)	87 (91)
Eosinophils/Leukocytes (Blood Smear) [%]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 1	Normal	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

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Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Eosinophils/Leukocytes (Blood Smear) [%]	Day 8	Normal	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
	Day 29	Normal	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 50	Normal	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Erythrocytes (Blood) [10^{12}/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	3 (25)	2 (17)	6 (17)	7 (7)
		Normal	11 (92)	9 (75)	10 (83)	30 (83)	89 (93)
	Day 1	Abnormal (not CS)	2 (17)	4 (33)	1 (8)	7 (19)	19 (20)
		Normal	10 (83)	8 (67)	11 (92)	29 (81)	77 (80)
	Day 2	Abnormal (not CS)	2 (17)	2 (17)	3 (25)	7 (19)	14 (15)
		Normal	10 (83)	10 (83)	9 (75)	29 (81)	82 (85)
	Day 8	Abnormal (not CS)	2 (17)	4 (33)	5 (42)	11 (31)	22 (23)
		Normal	10 (83)	8 (67)	7 (58)	25 (69)	74 (77)
	Day 29	Abnormal (not CS)	2 (17)	3 (25)	1 (8)	6 (17)	13 (14)
		Normal	10 (83)	9 (75)	11 (92)	30 (83)	81 (84)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

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Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Erythrocytes (Blood) [10^{12}/L]	Day 50	Abnormal (not CS)	2 (17)	5 (42)	3 (25)	10 (28)	21 (22)
		Normal	8 (67)	6 (50)	9 (75)	23 (64)	71 (74)
Hematocrit [L/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (6)	4 (4)
		Normal	12 (100)	11 (92)	11 (92)	34 (94)	92 (96)
	Day 1	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
		Normal	12 (100)	11 (92)	12 (100)	35 (97)	95 (99)
	Day 2	Abnormal (not CS)	2 (17)	0 (0)	1 (8)	3 (8)	4 (4)
		Normal	10 (83)	12 (100)	11 (92)	33 (92)	92 (96)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	3 (3)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	93 (97)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	4 (4)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	90 (94)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 50	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (6)	2 (2)
		Normal	10 (83)	10 (83)	11 (92)	31 (86)	90 (94)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

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Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Hemoglobin (Blood) [mmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	92 (96)
	Day 1	Abnormal (not CS)	2 (17)	3 (25)	1 (8)	6 (17)	14 (15)
		Normal	10 (83)	9 (75)	11 (92)	30 (83)	82 (85)
	Day 2	Abnormal (not CS)	3 (25)	0 (0)	1 (8)	4 (11)	10 (10)
		Normal	9 (75)	12 (100)	11 (92)	32 (89)	86 (90)
	Day 8	Abnormal (not CS)	2 (17)	3 (25)	2 (17)	7 (19)	20 (21)
		Normal	10 (83)	9 (75)	10 (83)	29 (81)	76 (79)
	Day 29	Abnormal (not CS)	1 (8)	2 (17)	1 (8)	4 (11)	11 (11)
		Normal	11 (92)	10 (83)	11 (92)	32 (89)	83 (86)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 50	Abnormal (not CS)	2 (17)	3 (25)	1 (8)	6 (17)	20 (21)
		Normal	8 (67)	8 (67)	11 (92)	27 (75)	72 (75)
Leukocytes (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	3 (8)	6 (6)
		Normal	11 (92)	11 (92)	11 (92)	33 (92)	90 (94)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

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Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Leukocytes (Blood) [10^9/L]	Day 1	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	9 (9)
		Normal	12 (100)	11 (92)	12 (100)	35 (97)	87 (91)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	3 (3)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	93 (97)
	Day 8	Abnormal (not CS)	3 (25)	1 (8)	2 (17)	6 (17)	14 (15)
		Normal	9 (75)	11 (92)	10 (83)	30 (83)	82 (85)
	Day 29	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	3 (8)	13 (14)
		Normal	11 (92)	11 (92)	11 (92)	33 (92)	81 (84)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 50	Abnormal (not CS)	2 (17)	1 (8)	2 (17)	5 (14)	15 (16)
		Normal	8 (67)	10 (83)	10 (83)	28 (78)	77 (80)
Lymphocytes (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	1 (8)	4 (33)	6 (17)	8 (8)
		Normal	11 (92)	11 (92)	8 (67)	30 (83)	85 (89)
	Day 1	Abnormal (not CS)	2 (17)	2 (17)	3 (25)	7 (19)	12 (13)
		Normal	10 (83)	10 (83)	9 (75)	29 (81)	82 (85)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 27 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Lymphocytes (Blood) [10^9/L]	Day 2	Abnormal (not CS)	3 (25)	2 (17)	9 (75)	14 (39)	30 (31)
		Normal	9 (75)	10 (83)	3 (25)	22 (61)	66 (69)
	Day 8	Abnormal (not CS)	1 (8)	2 (17)	1 (8)	4 (11)	8 (8)
		Normal	10 (83)	10 (83)	11 (92)	31 (86)	85 (89)
	Day 29	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	3 (8)	7 (7)
		Normal	11 (92)	11 (92)	11 (92)	33 (92)	83 (86)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 50	Abnormal (not CS)	1 (8)	1 (8)	2 (17)	4 (11)	8 (8)
		Normal	9 (75)	10 (83)	10 (83)	29 (81)	82 (85)
Lymphocytes (Blood Smear) [10^9/L]	Day -30 to 0	Missing	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Day 1	Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 8	Missing	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
	Day 29	Missing	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
	Day 50	Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Lymphocytes/Leukocytes (Blood) [%]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (6)	2 (2)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 28 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Lymphocytes/Leukocytes (Blood) [%]	Day -30 to 0	Normal	12 (100)	11 (92)	11 (92)	34 (94)	91 (95)
	Day 1	Abnormal (not CS)	0 (0)	2 (17)	2 (17)	4 (11)	7 (7)
		Normal	12 (100)	10 (83)	10 (83)	32 (89)	87 (91)
	Day 2	Abnormal (not CS)	0 (0)	1 (8)	4 (33)	5 (14)	11 (11)
		Normal	12 (100)	11 (92)	8 (67)	31 (86)	85 (89)
	Day 8	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (6)	2 (2)
		Normal	11 (92)	11 (92)	11 (92)	33 (92)	91 (95)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	87 (91)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	3 (3)
		Normal	9 (75)	11 (92)	11 (92)	31 (86)	87 (91)
Lymphocytes/Leukocytes (Blood Smear) [%]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 29 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Lymphocytes/Leukocytes (Blood Smear) [%]	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Monocytes (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	91 (95)
	Day 1	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
		Normal	12 (100)	11 (92)	12 (100)	35 (97)	92 (96)
	Day 2	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (6)	6 (6)
		Normal	12 (100)	11 (92)	11 (92)	34 (94)	90 (94)
	Day 8	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (6)	4 (4)
		Normal	11 (92)	11 (92)	11 (92)	33 (92)	89 (93)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	2 (6)	3 (3)
		Normal	12 (100)	12 (100)	10 (83)	34 (94)	87 (91)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 30 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Monocytes (Blood) [10^9/L]	Day 29	Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
		Normal	10 (83)	11 (92)	12 (100)	33 (92)	86 (90)
Monocytes (Blood Smear) [10^9/L]	Day -30 to 0	Missing	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Day 1	Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 8	Missing	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
	Day 29	Missing	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
	Day 50	Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Monocytes/Leukocytes (Blood) [%]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	91 (95)
	Day 1	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	2 (6)	5 (5)
		Normal	12 (100)	10 (83)	12 (100)	34 (94)	89 (93)
	Day 2	Abnormal (not CS)	1 (8)	1 (8)	2 (17)	4 (11)	10 (10)
		Normal	11 (92)	11 (92)	10 (83)	32 (89)	86 (90)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	4 (4)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 31 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Monocytes/Leukocytes (Blood) [%]	Day 8	Normal	10 (83)	12 (100)	12 (100)	34 (94)	89 (93)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	3 (3)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	87 (91)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	5 (5)
		Normal	9 (75)	11 (92)	12 (100)	32 (89)	85 (89)
Monocytes/Leukocytes (Blood Smear) [%]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 8	Normal	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
	Day 29	Normal	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 50	Normal	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Neutrophils (Blood) [10^9/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (6)	4 (4)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 32 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Neutrophils (Blood) [10^9/L]	Day -30 to 0	Normal	11 (92)	11 (92)	12 (100)	34 (94)	89 (93)
	Day 1	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (6)	8 (8)
		Normal	12 (100)	11 (92)	11 (92)	34 (94)	86 (90)
	Day 2	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	4 (4)
		Normal	12 (100)	11 (92)	12 (100)	35 (97)	92 (96)
	Day 8	Abnormal (not CS)	1 (8)	2 (17)	2 (17)	5 (14)	12 (13)
		Normal	10 (83)	10 (83)	10 (83)	30 (83)	81 (84)
	Day 29	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	3 (8)	11 (11)
		Normal	11 (92)	11 (92)	11 (92)	33 (92)	79 (82)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 50	Abnormal (not CS)	1 (8)	1 (8)	2 (17)	4 (11)	11 (11)
		Normal	9 (75)	10 (83)	10 (83)	29 (81)	79 (82)
Neutrophils (Blood Smear) [10^9/L]	Day -30 to 0	Missing	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
	Day 1	Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 8	Missing	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 33 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Neutrophils (Blood Smear) [10^9/L]	Day 29	Missing	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
	Day 50	Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Neutrophils/Leukocytes (Blood) [%]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	92 (96)
	Day 1	Abnormal (not CS)	0 (0)	2 (17)	1 (8)	3 (8)	3 (3)
		Normal	12 (100)	10 (83)	11 (92)	33 (92)	91 (95)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	3 (25)	3 (8)	5 (5)
		Normal	12 (100)	12 (100)	9 (75)	33 (92)	91 (95)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	4 (4)
		Normal	10 (83)	12 (100)	11 (92)	33 (92)	89 (93)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	2 (6)	5 (5)
		Normal	12 (100)	12 (100)	10 (83)	34 (94)	85 (89)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
		Normal	9 (75)	11 (92)	12 (100)	32 (89)	88 (92)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 34 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Neutrophils/Leukocytes (Blood Smear) [%]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 50	Normal	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
Platelets [10^9/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	2 (17)	1 (8)	3 (8)	5 (5)
		Normal	12 (100)	10 (83)	11 (92)	33 (92)	91 (95)
	Day 1	Abnormal (not CS)	2 (17)	2 (17)	1 (8)	5 (14)	9 (9)
		Normal	10 (83)	10 (83)	11 (92)	31 (86)	87 (91)
	Day 2	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (6)	5 (5)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 35 of 36)

Table 14.3.2-2.5.1-3: Laboratory: Abnormal and clinically significant values per visit (Hematology) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Platelets [10^9/L]	Day 2	Normal	12 (100)	11 (92)	11 (92)	34 (94)	91 (95)
	Day 8	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (6)	4 (4)
		Normal	12 (100)	11 (92)	11 (92)	34 (94)	92 (96)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	5 (5)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	89 (93)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 50	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	2 (6)	5 (5)
		Normal	10 (83)	9 (75)	12 (100)	31 (86)	87 (91)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 36 of 36)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Alanine Aminotransferase [U/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
		Normal	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	59 (98)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 8	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	59 (98)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	2 (17)	2 (17)	4 (7)
		Normal	12 (100)	12 (100)	12 (100)	10 (83)	10 (83)	56 (93)
	Day 50	Abnormal (not CS)	0 (0)	2 (17)	1 (8)	0 (0)	1 (8)	4 (7)
		Normal	11 (92)	10 (83)	11 (92)	12 (100)	11 (92)	55 (92)
Albumin [g/L]	Day -30 to 0	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 1	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 2	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 1 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Albumin [g/L]	Day 8	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 29	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 50	Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	59 (98)
Alkaline Phosphatase [U/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
		Normal	12 (100)	10 (83)	12 (100)	12 (100)	12 (100)	58 (97)
	Day 1	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	59 (98)
	Day 2	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
		Normal	12 (100)	10 (83)	12 (100)	12 (100)	12 (100)	58 (97)
	Day 8	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	59 (98)
	Day 29	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	1 (8)	1 (8)	4 (7)
		Normal	12 (100)	10 (83)	12 (100)	11 (92)	11 (92)	56 (93)
	Day 50	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
		Normal	11 (92)	10 (83)	12 (100)	12 (100)	12 (100)	57 (95)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 2 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Amylase [U/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	1 (8)	0 (0)	3 (5)
		Normal	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	57 (95)
	Day 1	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	1 (8)	2 (17)	5 (8)
		Normal	11 (92)	11 (92)	12 (100)	11 (92)	10 (83)	55 (92)
	Day 2	Abnormal (not CS)	2 (17)	1 (8)	0 (0)	0 (0)	1 (8)	4 (7)
		Normal	10 (83)	11 (92)	12 (100)	12 (100)	11 (92)	56 (93)
	Day 8	CS abnormal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Abnormal (not CS)	1 (8)	1 (8)	0 (0)	1 (8)	2 (17)	5 (8)
		Normal	11 (92)	11 (92)	12 (100)	11 (92)	10 (83)	55 (92)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (8)	2 (17)	4 (7)
		Normal	11 (92)	12 (100)	12 (100)	11 (92)	10 (83)	56 (93)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (17)	2 (17)	6 (10)
		Normal	10 (83)	12 (100)	11 (92)	10 (83)	10 (83)	53 (88)
Aspartate Aminotransferase [U/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 3 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Aspartate Aminotransferase [U/L]	Day 1	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (3)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	11 (92)	58 (97)
	Day 2	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 8	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	59 (98)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	59 (98)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		Normal	11 (92)	12 (100)	12 (100)	11 (92)	12 (100)	58 (97)
Bilirubin (Serum) [µmol/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (3)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	11 (92)	58 (97)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (3)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	11 (92)	58 (97)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	2 (17)	1 (8)	3 (5)
		Normal	12 (100)	12 (100)	12 (100)	10 (83)	11 (92)	57 (95)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 4 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Bilirubin (Serum) [µmol/L]	Day 8	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	59 (98)
	Day 29	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 50	Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	59 (98)
C Reactive Protein [mg/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	59 (98)
	Day 1	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	59 (98)
	Day 2	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (8)	0 (0)	2 (3)
		Normal	12 (100)	11 (92)	12 (100)	11 (92)	12 (100)	58 (97)
	Day 8	CS abnormal	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
		Abnormal (not CS)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
		Normal	11 (92)	10 (83)	12 (100)	12 (100)	12 (100)	57 (95)
	Day 29	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (3)
		Normal	12 (100)	11 (92)	11 (92)	12 (100)	12 (100)	58 (97)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 5 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
C Reactive Protein [mg/L]	Day 50	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	0 (0)	1 (8)	3 (5)
		Normal	11 (92)	10 (83)	12 (100)	12 (100)	11 (92)	56 (93)
Calcium [mmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		Normal	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	59 (98)
	Day 1	Abnormal (not CS)	1 (8)	2 (17)	0 (0)	0 (0)	1 (8)	4 (7)
		Normal	11 (92)	10 (83)	12 (100)	12 (100)	11 (92)	56 (93)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	59 (98)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (8)	2 (17)	4 (7)
		Normal	11 (92)	12 (100)	12 (100)	11 (92)	10 (83)	56 (93)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	10 (83)	12 (100)	12 (100)	12 (100)	12 (100)	58 (97)
Creatinine [µmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	1 (8)	3 (25)	6 (10)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 6 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Creatinine [µmol/L]	Day -30 to 0	Normal	12 (100)	12 (100)	10 (83)	11 (92)	9 (75)	54 (90)
	Day 1	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	2 (3)
		Normal	11 (92)	11 (92)	12 (100)	12 (100)	12 (100)	58 (97)
	Day 2	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	2 (3)
		Normal	11 (92)	11 (92)	12 (100)	12 (100)	12 (100)	58 (97)
	Day 8	Abnormal (not CS)	1 (8)	2 (17)	0 (0)	2 (17)	0 (0)	5 (8)
		Normal	11 (92)	10 (83)	12 (100)	10 (83)	12 (100)	55 (92)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (3)
		Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	58 (97)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	2 (17)	0 (0)	3 (5)
		Normal	11 (92)	12 (100)	11 (92)	10 (83)	12 (100)	56 (93)
Ferritin [µg/L]	Day -30 to 0	Abnormal (not CS)	2 (17)	3 (25)	2 (17)	0 (0)	1 (8)	8 (13)
		Normal	10 (83)	9 (75)	10 (83)	12 (100)	11 (92)	52 (87)
	Day 1	Abnormal (not CS)	4 (33)	3 (25)	2 (17)	0 (0)	0 (0)	9 (15)
		Normal	8 (67)	9 (75)	10 (83)	12 (100)	12 (100)	51 (85)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 7 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Ferritin [µg/L]	Day 2	Abnormal (not CS)	4 (33)	3 (25)	1 (8)	1 (8)	0 (0)	9 (15)
		Normal	8 (67)	9 (75)	11 (92)	11 (92)	12 (100)	51 (85)
	Day 8	Abnormal (not CS)	4 (33)	2 (17)	3 (25)	0 (0)	1 (8)	10 (17)
		Normal	8 (67)	10 (83)	9 (75)	12 (100)	11 (92)	50 (83)
	Day 29	Abnormal (not CS)	3 (25)	3 (25)	3 (25)	0 (0)	1 (8)	10 (17)
		Normal	9 (75)	9 (75)	9 (75)	12 (100)	11 (92)	50 (83)
	Day 50	Abnormal (not CS)	3 (25)	3 (25)	4 (33)	1 (8)	2 (17)	13 (22)
		Normal	8 (67)	9 (75)	8 (67)	11 (92)	10 (83)	46 (77)
Follicle Stimulating Hormone [IU/L]	Day -30 to 0	Missing	5 (42)	7 (58)	7 (58)	10 (83)	4 (33)	33 (55)
Gamma Glutamyl Transferase [U/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	59 (98)
	Day 1	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	59 (98)
	Day 2	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	59 (98)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 8 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Gamma Glutamyl Transferase [U/L]	Day 8	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	59 (98)
	Day 29	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	59 (98)
	Day 50	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	11 (92)	11 (92)	12 (100)	12 (100)	12 (100)	58 (97)
Glucose (Blood) [mmol/L]	Day -30 to 0	Abnormal (not CS)	2 (17)	3 (25)	2 (17)	4 (33)	6 (50)	17 (28)
		Normal	10 (83)	9 (75)	10 (83)	8 (67)	6 (50)	43 (72)
	Day 1	Abnormal (not CS)	4 (33)	3 (25)	4 (33)	4 (33)	6 (50)	21 (35)
		Normal	8 (67)	9 (75)	8 (67)	8 (67)	6 (50)	39 (65)
	Day 2	Abnormal (not CS)	2 (17)	3 (25)	4 (33)	5 (42)	3 (25)	17 (28)
		Normal	10 (83)	9 (75)	8 (67)	7 (58)	9 (75)	43 (72)
	Day 8	Abnormal (not CS)	4 (33)	1 (8)	2 (17)	5 (42)	6 (50)	18 (30)
		Normal	8 (67)	11 (92)	10 (83)	7 (58)	6 (50)	42 (70)
	Day 29	Abnormal (not CS)	3 (25)	2 (17)	2 (17)	5 (42)	6 (50)	18 (30)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 9 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Glucose (Blood) [mmol/L]	Day 29	Normal	9 (75)	10 (83)	10 (83)	7 (58)	6 (50)	42 (70)
	Day 50	Abnormal (not CS)	3 (25)	3 (25)	1 (8)	2 (17)	3 (25)	12 (20)
		Normal	8 (67)	9 (75)	11 (92)	10 (83)	9 (75)	47 (78)
Lipase [U/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	1 (8)	0 (0)	3 (5)
		Normal	12 (100)	11 (92)	11 (92)	11 (92)	12 (100)	57 (95)
	Day 1	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	4 (7)
		Normal	12 (100)	11 (92)	11 (92)	11 (92)	11 (92)	56 (93)
	Day 2	Abnormal (not CS)	2 (17)	2 (17)	2 (17)	0 (0)	0 (0)	6 (10)
		Normal	10 (83)	10 (83)	10 (83)	12 (100)	12 (100)	54 (90)
	Day 8	CS abnormal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Abnormal (not CS)	1 (8)	1 (8)	1 (8)	1 (8)	2 (17)	6 (10)
		Normal	11 (92)	11 (92)	11 (92)	11 (92)	10 (83)	54 (90)
	Day 29	Abnormal (not CS)	1 (8)	2 (17)	1 (8)	0 (0)	2 (17)	6 (10)
		Normal	11 (92)	10 (83)	11 (92)	12 (100)	10 (83)	54 (90)
	Day 50	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 10 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Lipase [U/L]	Day 50	Normal	11 (92)	11 (92)	12 (100)	12 (100)	12 (100)	58 (97)
Potassium [mmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		Normal	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	59 (98)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		Normal	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	59 (98)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	59 (98)
Sodium [mmol/L]	Day -30 to 0	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 11 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Sodium [mmol/L]	Day 1	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	59 (98)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	10 (83)	12 (100)	12 (100)	12 (100)	12 (100)	58 (97)
Urea Nitrogen [mmol/L]	Day -30 to 0	Abnormal (not CS)	2 (17)	0 (0)	1 (8)	0 (0)	0 (0)	3 (5)
		Normal	10 (83)	12 (100)	11 (92)	12 (100)	12 (100)	57 (95)
	Day 1	Abnormal (not CS)	1 (8)	1 (8)	3 (25)	0 (0)	0 (0)	5 (8)
		Normal	11 (92)	11 (92)	9 (75)	12 (100)	12 (100)	55 (92)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	2 (17)	0 (0)	1 (8)	4 (7)
		Normal	11 (92)	12 (100)	9 (75)	12 (100)	11 (92)	55 (92)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 12 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Urea Nitrogen [mmol/L]	Day 2	Missing	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
	Day 8	Abnormal (not CS)	1 (8)	3 (25)	2 (17)	0 (0)	1 (8)	7 (12)
		Normal	11 (92)	9 (75)	10 (83)	12 (100)	11 (92)	53 (88)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	3 (25)	2 (17)	1 (8)	6 (10)
		Normal	12 (100)	12 (100)	9 (75)	10 (83)	11 (92)	54 (90)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (17)	1 (8)	5 (8)
		Normal	10 (83)	12 (100)	11 (92)	10 (83)	11 (92)	54 (90)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 13 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Alanine Aminotransferase [U/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
		Normal	12 (100)	11 (92)	12 (100)	35 (97)	95 (99)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	94 (98)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	95 (99)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	94 (98)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	5 (5)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	91 (95)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
		Normal	10 (83)	11 (92)	12 (100)	33 (92)	88 (92)
Albumin [g/L]	Day -30 to 0	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 1	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 2	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 14 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Albumin [g/L]	Day 8	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 29	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 50	Normal	10 (83)	11 (92)	12 (100)	33 (92)	92 (96)
Alkaline Phosphatase [U/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	4 (4)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	92 (96)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	3 (3)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	93 (97)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	4 (4)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	92 (96)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	3 (3)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	93 (97)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	6 (6)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	90 (94)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
		Normal	10 (83)	11 (92)	11 (92)	32 (89)	89 (93)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 15 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Amylase [U/L]	Day -30 to 0	Abnormal (not CS)	2 (17)	0 (0)	2 (17)	4 (11)	7 (7)
		Normal	10 (83)	12 (100)	10 (83)	32 (89)	89 (93)
	Day 1	Abnormal (not CS)	2 (17)	0 (0)	1 (8)	3 (8)	8 (8)
		Normal	10 (83)	12 (100)	11 (92)	33 (92)	88 (92)
	Day 2	Abnormal (not CS)	2 (17)	0 (0)	1 (8)	3 (8)	7 (7)
		Normal	10 (83)	12 (100)	11 (92)	33 (92)	89 (93)
	Day 8	CS abnormal	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
		Abnormal (not CS)	2 (17)	1 (8)	1 (8)	4 (11)	9 (9)
		Normal	10 (83)	10 (83)	11 (92)	31 (86)	86 (90)
	Day 29	Abnormal (not CS)	4 (33)	0 (0)	2 (17)	6 (17)	10 (10)
		Normal	8 (67)	12 (100)	10 (83)	30 (83)	86 (90)
	Day 50	Abnormal (not CS)	3 (25)	0 (0)	2 (17)	5 (14)	11 (11)
		Normal	7 (58)	11 (92)	10 (83)	28 (78)	81 (84)
Aspartate Aminotransferase [U/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
		Normal	12 (100)	11 (92)	12 (100)	35 (97)	95 (99)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 16 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Aspartate Aminotransferase [U/L]	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
	Day 2	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	95 (99)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	95 (99)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		Normal	10 (83)	11 (92)	11 (92)	32 (89)	90 (94)
Bilirubin (Serum) [µmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	2 (6)	5 (5)
		Normal	12 (100)	12 (100)	10 (83)	34 (94)	91 (95)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 17 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Bilirubin (Serum) [µmol/L]	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	95 (99)
	Day 29	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 50	Normal	10 (83)	11 (92)	12 (100)	33 (92)	92 (96)
C Reactive Protein [mg/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	2 (2)
		Normal	12 (100)	11 (92)	12 (100)	35 (97)	94 (98)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	95 (99)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	3 (25)	3 (8)	5 (5)
		Normal	12 (100)	12 (100)	9 (75)	33 (92)	91 (95)
	Day 8	CS abnormal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
		Normal	12 (100)	11 (92)	12 (100)	35 (97)	92 (96)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	4 (4)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	92 (96)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 18 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
C Reactive Protein [mg/L]	Day 50	Abnormal (not CS)	1 (8)	2 (17)	0 (0)	3 (8)	6 (6)
		Normal	9 (75)	9 (75)	12 (100)	30 (83)	86 (90)
Calcium [mmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	94 (98)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	5 (5)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	91 (95)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	95 (99)
	Day 8	Abnormal (not CS)	2 (17)	0 (0)	1 (8)	3 (8)	4 (4)
		Normal	10 (83)	12 (100)	11 (92)	33 (92)	92 (96)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	5 (5)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	91 (95)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		Normal	10 (83)	11 (92)	11 (92)	32 (89)	90 (94)
Creatinine [µmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	2 (17)	3 (8)	9 (9)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 19 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Creatinine [µmol/L]	Day -30 to 0	Normal	12 (100)	11 (92)	10 (83)	33 (92)	87 (91)
	Day 1	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
		Normal	12 (100)	11 (92)	12 (100)	35 (97)	93 (97)
	Day 2	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
		Normal	12 (100)	11 (92)	12 (100)	35 (97)	93 (97)
	Day 8	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	3 (8)	8 (8)
		Normal	11 (92)	11 (92)	11 (92)	33 (92)	88 (92)
	Day 29	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (6)	4 (4)
		Normal	12 (100)	11 (92)	11 (92)	34 (94)	92 (96)
	Day 50	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (6)	5 (5)
		Normal	10 (83)	10 (83)	11 (92)	31 (86)	87 (91)
Ferritin [µg/L]	Day -30 to 0	Abnormal (not CS)	2 (17)	1 (8)	3 (25)	6 (17)	14 (15)
		Normal	10 (83)	11 (92)	9 (75)	30 (83)	82 (85)
	Day 1	Abnormal (not CS)	1 (8)	2 (17)	4 (33)	7 (19)	16 (17)
		Normal	11 (92)	10 (83)	8 (67)	29 (81)	80 (83)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 20 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Ferritin [µg/L]	Day 2	Abnormal (not CS)	0 (0)	1 (8)	4 (33)	5 (14)	14 (15)
		Normal	12 (100)	11 (92)	8 (67)	31 (86)	82 (85)
	Day 8	Abnormal (not CS)	0 (0)	1 (8)	4 (33)	5 (14)	15 (16)
		Normal	12 (100)	11 (92)	8 (67)	31 (86)	81 (84)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	4 (33)	5 (14)	15 (16)
		Normal	11 (92)	12 (100)	8 (67)	31 (86)	81 (84)
	Day 50	Abnormal (not CS)	1 (8)	1 (8)	3 (25)	5 (14)	18 (19)
		Normal	9 (75)	10 (83)	9 (75)	28 (78)	74 (77)
Follicle Stimulating Hormone [IU/L]	Day -30 to 0	Missing	2 (17)	6 (50)	5 (42)	13 (36)	46 (48)
Gamma Glutamyl Transferase [U/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (6)	3 (3)
		Normal	11 (92)	11 (92)	12 (100)	34 (94)	93 (97)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	95 (99)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	95 (99)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 21 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Gamma Glutamyl Transferase [U/L]	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	95 (99)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	94 (98)
	Day 50	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (6)	3 (3)
		Normal	9 (75)	10 (83)	12 (100)	31 (86)	89 (93)
Glucose (Blood) [mmol/L]	Day -30 to 0	Abnormal (not CS)	5 (42)	10 (83)	4 (33)	19 (53)	36 (38)
		Normal	7 (58)	2 (17)	8 (67)	17 (47)	60 (63)
	Day 1	Abnormal (not CS)	3 (25)	9 (75)	3 (25)	15 (42)	36 (38)
		Normal	9 (75)	3 (25)	9 (75)	21 (58)	60 (63)
	Day 2	Abnormal (not CS)	2 (17)	9 (75)	5 (42)	16 (44)	33 (34)
		Normal	10 (83)	3 (25)	7 (58)	20 (56)	63 (66)
	Day 8	Abnormal (not CS)	4 (33)	9 (75)	3 (25)	16 (44)	34 (35)
		Normal	8 (67)	3 (25)	9 (75)	20 (56)	62 (65)
	Day 29	Abnormal (not CS)	4 (33)	10 (83)	6 (50)	20 (56)	38 (40)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 22 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Glucose (Blood) [mmol/L]	Day 29	Normal	8 (67)	2 (17)	6 (50)	16 (44)	58 (60)
	Day 50	Abnormal (not CS)	4 (33)	7 (58)	7 (58)	18 (50)	30 (31)
		Normal	6 (50)	4 (33)	5 (42)	15 (42)	62 (65)
Lipase [U/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	3 (8)	6 (6)
		Normal	11 (92)	11 (92)	11 (92)	33 (92)	90 (94)
	Day 1	Abnormal (not CS)	2 (17)	2 (17)	1 (8)	5 (14)	9 (9)
		Normal	10 (83)	10 (83)	11 (92)	31 (86)	87 (91)
	Day 2	Abnormal (not CS)	2 (17)	1 (8)	1 (8)	4 (11)	10 (10)
		Normal	10 (83)	11 (92)	11 (92)	32 (89)	86 (90)
	Day 8	CS abnormal	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
		Abnormal (not CS)	0 (0)	3 (25)	1 (8)	4 (11)	10 (10)
		Normal	12 (100)	8 (67)	11 (92)	31 (86)	85 (89)
	Day 29	Abnormal (not CS)	2 (17)	2 (17)	1 (8)	5 (14)	11 (11)
		Normal	10 (83)	10 (83)	11 (92)	31 (86)	85 (89)
	Day 50	Abnormal (not CS)	3 (25)	2 (17)	1 (8)	6 (17)	7 (7)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 23 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Lipase [U/L]	Day 50	Normal	7 (58)	9 (75)	11 (92)	27 (75)	85 (89)
Potassium [mmol/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	3 (3)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	93 (97)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	94 (98)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	95 (99)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	2 (2)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	94 (98)
	Day 29	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (6)	2 (2)
		Normal	12 (100)	11 (92)	11 (92)	34 (94)	94 (98)
	Day 50	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
		Normal	10 (83)	10 (83)	12 (100)	32 (89)	91 (95)
Sodium [mmol/L]	Day -30 to 0	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 1	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 24 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Sodium [mmol/L]	Day 1	Normal	12 (100)	11 (92)	12 (100)	35 (97)	95 (99)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	95 (99)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	94 (98)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	95 (99)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	10 (83)	11 (92)	12 (100)	33 (92)	91 (95)
Urea Nitrogen [mmol/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (6)	5 (5)
		Normal	11 (92)	11 (92)	12 (100)	34 (94)	91 (95)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	7 (7)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	89 (93)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	91 (95)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 25 of 26)

Table 14.3.2-2.5.2-3: Laboratory: Abnormal and clinically significant values per visit (Chemistry) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Urea Nitrogen [mmol/L]	Day 2	Missing	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	9 (9)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	87 (91)
	Day 29	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (6)	8 (8)
		Normal	11 (92)	11 (92)	12 (100)	34 (94)	88 (92)
	Day 50	Abnormal (not CS)	2 (17)	0 (0)	1 (8)	3 (8)	8 (8)
		Normal	8 (67)	11 (92)	11 (92)	30 (83)	84 (88)

The denominator for the percentage calculation is N. Follicle Stimulating Hormone is only collected for women.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 26 of 26)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Bacteria [/HPF]	Day -30 to 0	Abnormal (not CS)	2 (17)	5 (42)	2 (17)	4 (33)	1 (8)	14 (23)
		Normal	0 (0)	0 (0)	1 (8)	3 (25)	0 (0)	4 (7)
		Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 1	Abnormal (not CS)	2 (17)	2 (17)	3 (25)	3 (25)	0 (0)	10 (17)
		Normal	0 (0)	0 (0)	0 (0)	4 (33)	0 (0)	4 (7)
		Missing	0 (0)	2 (17)	1 (8)	0 (0)	0 (0)	3 (5)
	Day 2	Abnormal (not CS)	2 (17)	3 (25)	1 (8)	3 (25)	3 (25)	12 (20)
		Normal	0 (0)	1 (8)	1 (8)	1 (8)	0 (0)	3 (5)
		Missing	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (3)
	Day 8	Abnormal (not CS)	2 (17)	3 (25)	3 (25)	2 (17)	1 (8)	11 (18)
		Normal	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)
		Missing	1 (8)	0 (0)	1 (8)	1 (8)	0 (0)	3 (5)
	Day 29	Abnormal (not CS)	1 (8)	1 (8)	4 (33)	3 (25)	1 (8)	10 (17)
		Normal	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	3 (5)
		Missing	1 (8)	1 (8)	1 (8)	0 (0)	1 (8)	4 (7)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 1 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Bacteria [/HPF]	Day 50	Abnormal (not CS)	0 (0)	5 (42)	0 (0)	3 (25)	1 (8)	9 (15)
		Normal	1 (8)	0 (0)	0 (0)	1 (8)	0 (0)	2 (3)
		Missing	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (3)
Bilirubin (Urine) [µmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	2 (17)	0 (0)	3 (25)	6 (10)
		Normal	12 (100)	11 (92)	10 (83)	12 (100)	9 (75)	54 (90)
	Day 1	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	1 (8)	1 (8)	4 (7)
		Normal	12 (100)	10 (83)	12 (100)	11 (92)	11 (92)	56 (93)
	Day 2	CS abnormal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Abnormal (not CS)	0 (0)	1 (8)	2 (17)	0 (0)	0 (0)	3 (5)
		Normal	12 (100)	11 (92)	10 (83)	12 (100)	12 (100)	57 (95)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	3 (25)	1 (8)	1 (8)	6 (10)
		Normal	11 (92)	12 (100)	9 (75)	11 (92)	11 (92)	54 (90)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	5 (42)	0 (0)	2 (17)	7 (12)
		Normal	12 (100)	12 (100)	7 (58)	12 (100)	10 (83)	53 (88)
	Day 50	Abnormal (not CS)	0 (0)	1 (8)	2 (17)	0 (0)	3 (25)	6 (10)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 2 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Bilirubin (Urine) [µmol/L]	Day 50	Normal	11 (92)	11 (92)	10 (83)	12 (100)	9 (75)	53 (88)
Casts [/HPF]	Day -30 to 0	Normal	2 (17)	5 (42)	3 (25)	7 (58)	1 (8)	18 (30)
		Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 1	Normal	2 (17)	2 (17)	3 (25)	7 (58)	0 (0)	14 (23)
		Missing	0 (0)	2 (17)	1 (8)	0 (0)	0 (0)	3 (5)
	Day 2	Normal	2 (17)	3 (25)	2 (17)	4 (33)	3 (25)	14 (23)
		Missing	0 (0)	1 (8)	1 (8)	1 (8)	0 (0)	3 (5)
	Day 8	Normal	2 (17)	1 (8)	3 (25)	3 (25)	2 (17)	11 (18)
		Missing	1 (8)	2 (17)	1 (8)	1 (8)	0 (0)	5 (8)
	Day 29	Normal	1 (8)	2 (17)	4 (33)	2 (17)	2 (17)	11 (18)
		Missing	1 (8)	1 (8)	1 (8)	2 (17)	1 (8)	6 (10)
	Day 50	Normal	1 (8)	3 (25)	0 (0)	4 (33)	1 (8)	9 (15)
		Missing	0 (0)	3 (25)	1 (8)	0 (0)	0 (0)	4 (7)
Crystals [/HPF]	Day -30 to 0	Abnormal (not CS)	0 (0)	2 (17)	1 (8)	1 (8)	2 (17)	6 (10)
		Normal	2 (17)	3 (25)	3 (25)	6 (50)	0 (0)	14 (23)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 3 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Crystals [/HPF]	Day 1	Abnormal (not CS)	0 (0)	2 (17)	2 (17)	2 (17)	0 (0)	6 (10)
		Normal	2 (17)	1 (8)	2 (17)	5 (42)	0 (0)	10 (17)
		Missing	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	1 (8)	0 (0)	3 (5)
		Normal	1 (8)	3 (25)	2 (17)	4 (33)	3 (25)	13 (22)
		Missing	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	2 (17)	1 (8)	0 (0)	4 (7)
		Normal	2 (17)	1 (8)	2 (17)	3 (25)	2 (17)	10 (17)
		Missing	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
	Day 29	Abnormal (not CS)	1 (8)	1 (8)	2 (17)	1 (8)	2 (17)	7 (12)
		Normal	1 (8)	2 (17)	3 (25)	1 (8)	1 (8)	8 (13)
		Missing	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (3)
	Day 50	Abnormal (not CS)	1 (8)	2 (17)	1 (8)	2 (17)	0 (0)	6 (10)
		Normal	0 (0)	2 (17)	0 (0)	2 (17)	1 (8)	5 (8)
		Missing	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 4 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Epithelial Cells [/HPF]	Day -30 to 0	Abnormal (not CS)	2 (17)	3 (25)	0 (0)	6 (50)	1 (8)	12 (20)
		Normal	0 (0)	2 (17)	3 (25)	1 (8)	0 (0)	6 (10)
		Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 1	Abnormal (not CS)	2 (17)	1 (8)	3 (25)	1 (8)	0 (0)	7 (12)
		Normal	0 (0)	2 (17)	0 (0)	6 (50)	0 (0)	8 (13)
		Missing	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (3)
	Day 2	Abnormal (not CS)	1 (8)	2 (17)	0 (0)	1 (8)	0 (0)	4 (7)
		Normal	1 (8)	1 (8)	2 (17)	3 (25)	3 (25)	10 (17)
		Missing	0 (0)	1 (8)	1 (8)	1 (8)	0 (0)	3 (5)
	Day 8	Abnormal (not CS)	1 (8)	2 (17)	2 (17)	1 (8)	1 (8)	7 (12)
		Normal	1 (8)	0 (0)	1 (8)	2 (17)	1 (8)	5 (8)
		Missing	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	4 (7)
	Day 29	Abnormal (not CS)	1 (8)	1 (8)	2 (17)	1 (8)	1 (8)	6 (10)
		Normal	0 (0)	1 (8)	2 (17)	1 (8)	2 (17)	6 (10)
		Missing	1 (8)	1 (8)	1 (8)	2 (17)	0 (0)	5 (8)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 5 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Epithelial Cells [/HPF]	Day 50	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	1 (8)	0 (0)	3 (5)
		Normal	1 (8)	1 (8)	0 (0)	3 (25)	1 (8)	6 (10)
		Missing	0 (0)	3 (25)	1 (8)	0 (0)	0 (0)	4 (7)
Erythrocytes (Urine) [/HPF]	Day -30 to 0	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	2 (3)
		Normal	1 (8)	4 (33)	3 (25)	7 (58)	1 (8)	16 (27)
		Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 1	Abnormal (not CS)	0 (0)	2 (17)	3 (25)	1 (8)	0 (0)	6 (10)
		Normal	2 (17)	1 (8)	0 (0)	6 (50)	0 (0)	9 (15)
		Missing	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (3)
	Day 2	Abnormal (not CS)	2 (17)	1 (8)	0 (0)	2 (17)	1 (8)	6 (10)
		Normal	0 (0)	3 (25)	2 (17)	2 (17)	2 (17)	9 (15)
		Missing	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (3)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		Normal	2 (17)	1 (8)	3 (25)	2 (17)	2 (17)	10 (17)
		Missing	1 (8)	2 (17)	1 (8)	1 (8)	0 (0)	5 (8)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 6 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Erythrocytes (Urine) [/HPF]	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	3 (5)
		Normal	1 (8)	2 (17)	4 (33)	1 (8)	0 (0)	8 (13)
		Missing	1 (8)	1 (8)	1 (8)	2 (17)	1 (8)	6 (10)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	1 (8)	3 (25)	0 (0)	4 (33)	1 (8)	9 (15)
		Missing	0 (0)	3 (25)	1 (8)	0 (0)	0 (0)	4 (7)
Glucose (Urine)	Day -30 to 0	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 1	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 2	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 8	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 29	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 50	Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	59 (98)
Hemoglobin (Urine) [10^6/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	4 (7)
		Normal	12 (100)	11 (92)	11 (92)	11 (92)	11 (92)	56 (93)
	Day 1	Abnormal (not CS)	1 (8)	3 (25)	4 (33)	5 (42)	0 (0)	13 (22)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 7 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Hemoglobin (Urine) [10^6/L]	Day 1	Normal	11 (92)	9 (75)	8 (67)	7 (58)	12 (100)	47 (78)
	Day 2	CS abnormal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Abnormal (not CS)	1 (8)	2 (17)	2 (17)	5 (42)	2 (17)	12 (20)
		Normal	11 (92)	10 (83)	10 (83)	7 (58)	10 (83)	48 (80)
	Day 8	Abnormal (not CS)	2 (17)	1 (8)	3 (25)	2 (17)	1 (8)	9 (15)
		Normal	10 (83)	11 (92)	9 (75)	10 (83)	11 (92)	51 (85)
	Day 29	Abnormal (not CS)	0 (0)	3 (25)	3 (25)	3 (25)	3 (25)	12 (20)
		Normal	12 (100)	9 (75)	9 (75)	9 (75)	9 (75)	48 (80)
	Day 50	Abnormal (not CS)	1 (8)	3 (25)	0 (0)	1 (8)	0 (0)	5 (8)
		Normal	10 (83)	9 (75)	12 (100)	11 (92)	12 (100)	54 (90)
Ketones [mmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	3 (5)
		Normal	12 (100)	12 (100)	12 (100)	11 (92)	10 (83)	57 (95)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (3)
		Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	58 (97)
	Day 2	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	1 (8)	0 (0)	3 (5)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 8 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Ketones [mmol/L]	Day 2	Normal	12 (100)	11 (92)	11 (92)	11 (92)	12 (100)	57 (95)
	Day 8	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	1 (8)	0 (0)	4 (7)
		Normal	11 (92)	11 (92)	11 (92)	11 (92)	12 (100)	56 (93)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	5 (42)	0 (0)	1 (8)	7 (12)
		Normal	11 (92)	12 (100)	7 (58)	12 (100)	11 (92)	53 (88)
	Day 50	Abnormal (not CS)	2 (17)	1 (8)	0 (0)	2 (17)	1 (8)	6 (10)
		Normal	9 (75)	11 (92)	12 (100)	10 (83)	11 (92)	53 (88)
Leukocytes (Urine - Dipstick) [10^6/L]	Day -30 to 0	Abnormal (not CS)	2 (17)	3 (25)	2 (17)	5 (42)	2 (17)	14 (23)
		Normal	10 (83)	9 (75)	10 (83)	7 (58)	10 (83)	46 (77)
	Day 1	Abnormal (not CS)	1 (8)	3 (25)	1 (8)	3 (25)	0 (0)	8 (13)
		Normal	11 (92)	9 (75)	11 (92)	9 (75)	12 (100)	52 (87)
	Day 2	CS abnormal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Abnormal (not CS)	1 (8)	3 (25)	1 (8)	2 (17)	2 (17)	9 (15)
		Normal	11 (92)	9 (75)	11 (92)	10 (83)	10 (83)	51 (85)
	Day 8	Abnormal (not CS)	0 (0)	2 (17)	3 (25)	4 (33)	2 (17)	11 (18)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 9 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Leukocytes (Urine - Dipstick) [10^6/L]	Day 8	Normal	12 (100)	10 (83)	9 (75)	8 (67)	10 (83)	49 (82)
	Day 29	Abnormal (not CS)	1 (8)	2 (17)	3 (25)	3 (25)	1 (8)	10 (17)
		Normal	11 (92)	10 (83)	9 (75)	9 (75)	11 (92)	50 (83)
	Day 50	Abnormal (not CS)	1 (8)	4 (33)	1 (8)	3 (25)	1 (8)	10 (17)
		Normal	10 (83)	8 (67)	11 (92)	9 (75)	11 (92)	49 (82)
Leukocytes (Urine - Microscopy) [/HPF]	Day -30 to 0	Abnormal (not CS)	1 (8)	3 (25)	0 (0)	4 (33)	1 (8)	9 (15)
		Normal	1 (8)	2 (17)	3 (25)	3 (25)	0 (0)	9 (15)
		Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (3)
		Normal	2 (17)	2 (17)	2 (17)	6 (50)	0 (0)	12 (20)
		Missing	0 (0)	2 (17)	1 (8)	0 (0)	0 (0)	3 (5)
	Day 2	CS abnormal	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Abnormal (not CS)	1 (8)	3 (25)	0 (0)	1 (8)	0 (0)	5 (8)
		Normal	1 (8)	0 (0)	2 (17)	3 (25)	3 (25)	9 (15)
		Missing	0 (0)	1 (8)	1 (8)	1 (8)	0 (0)	3 (5)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 10 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Leukocytes (Urine - Microscopy) [/HPF]	Day 8	Abnormal (not CS)	0 (0)	1 (8)	2 (17)	2 (17)	2 (17)	7 (12)
		Normal	2 (17)	0 (0)	1 (8)	1 (8)	0 (0)	4 (7)
		Missing	1 (8)	2 (17)	1 (8)	1 (8)	0 (0)	5 (8)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	2 (17)	0 (0)	4 (7)
		Normal	1 (8)	2 (17)	2 (17)	1 (8)	2 (17)	8 (13)
		Missing	1 (8)	1 (8)	1 (8)	1 (8)	1 (8)	5 (8)
	Day 50	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (8)	1 (8)	3 (5)
		Normal	1 (8)	2 (17)	0 (0)	3 (25)	0 (0)	6 (10)
		Missing	0 (0)	3 (25)	1 (8)	0 (0)	0 (0)	4 (7)
Nitrite	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (3)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	11 (92)	58 (97)
	Day 1	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	12 (100)	59 (98)
	Day 2	Abnormal (not CS)	0 (0)	2 (17)	1 (8)	0 (0)	1 (8)	4 (7)
		Normal	12 (100)	10 (83)	11 (92)	12 (100)	11 (92)	56 (93)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 11 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Nitrite	Day 8	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (3)
		Normal	12 (100)	11 (92)	12 (100)	12 (100)	11 (92)	58 (97)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
		Normal	12 (100)	12 (100)	12 (100)	11 (92)	12 (100)	59 (98)
	Day 50	Abnormal (not CS)	0 (0)	3 (25)	0 (0)	0 (0)	1 (8)	4 (7)
		Normal	11 (92)	9 (75)	12 (100)	12 (100)	11 (92)	55 (92)
pH	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	0 (0)	0 (0)	2 (3)
		Normal	12 (100)	11 (92)	11 (92)	12 (100)	12 (100)	58 (97)
	Day 1	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	1 (8)	3 (25)	6 (10)
		Normal	12 (100)	10 (83)	12 (100)	11 (92)	9 (75)	54 (90)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	3 (5)
		Normal	12 (100)	12 (100)	12 (100)	11 (92)	10 (83)	57 (95)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	2 (3)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	10 (83)	58 (97)
	Day 29	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	0 (0)	1 (8)	3 (5)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 12 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
pH	Day 29	Normal	12 (100)	10 (83)	12 (100)	12 (100)	11 (92)	57 (95)
	Day 50	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	0 (0)	1 (8)	2 (3)
		Normal	11 (92)	11 (92)	12 (100)	12 (100)	11 (92)	57 (95)
Protein [mg/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	1 (8)	1 (8)	4 (7)
		Normal	12 (100)	11 (92)	11 (92)	11 (92)	11 (92)	56 (93)
	Day 1	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	1 (8)	0 (0)	3 (5)
		Normal	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	57 (95)
	Day 2	Abnormal (not CS)	0 (0)	2 (17)	1 (8)	0 (0)	0 (0)	3 (5)
		Normal	12 (100)	10 (83)	11 (92)	12 (100)	12 (100)	57 (95)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (3)
		Normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	2 (17)	2 (17)	1 (8)	6 (10)
		Normal	11 (92)	12 (100)	10 (83)	10 (83)	11 (92)	54 (90)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
		Normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 13 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Round Epithelial Cells [/HPF]	Day -30 to 0	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	0 (0)	0 (0)	2 (3)
		Normal	2 (17)	3 (25)	3 (25)	7 (58)	1 (8)	16 (27)
		Missing	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
	Day 1	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	3 (25)	0 (0)	4 (7)
		Normal	2 (17)	1 (8)	3 (25)	4 (33)	0 (0)	10 (17)
		Missing	0 (0)	2 (17)	1 (8)	0 (0)	0 (0)	3 (5)
	Day 2	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (17)	0 (0)	4 (7)
		Normal	1 (8)	2 (17)	2 (17)	2 (17)	3 (25)	10 (17)
		Missing	0 (0)	1 (8)	1 (8)	1 (8)	0 (0)	3 (5)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	2 (3)
		Normal	2 (17)	1 (8)	3 (25)	3 (25)	0 (0)	9 (15)
		Missing	1 (8)	2 (17)	1 (8)	1 (8)	0 (0)	5 (8)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	3 (5)
		Normal	1 (8)	2 (17)	3 (25)	2 (17)	1 (8)	9 (15)
		Missing	1 (8)	1 (8)	1 (8)	2 (17)	0 (0)	5 (8)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

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Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Round Epithelial Cells [/HPF]	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	1 (8)	3 (25)	0 (0)	4 (33)	1 (8)	9 (15)
		Missing	0 (0)	3 (25)	1 (8)	0 (0)	0 (0)	4 (7)
Specific Gravity	Day -30 to 0	Abnormal (not CS)	3 (25)	2 (17)	0 (0)	0 (0)	0 (0)	5 (8)
		Normal	9 (75)	10 (83)	12 (100)	12 (100)	12 (100)	55 (92)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	2 (17)	0 (0)	2 (3)
		Normal	12 (100)	12 (100)	12 (100)	10 (83)	12 (100)	58 (97)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	59 (98)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 29	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (3)
		Normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
		Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	59 (98)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

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Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Younger dose ranging cohorts					
Parameter [Unit]	Visit		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Urobilinogen [µmol/L]	Day -30 to 0	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 1	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 2	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 8	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
		Normal	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	59 (98)
	Day 50	Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	59 (98)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

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Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Bacteria [/HPF]	Day -30 to 0	Abnormal (not CS)	0 (0)	3 (25)	1 (8)	4 (11)	18 (19)
		Normal	1 (8)	2 (17)	4 (33)	7 (19)	11 (11)
		Missing	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)
	Day 1	Abnormal (not CS)	1 (8)	1 (8)	3 (25)	5 (14)	15 (16)
		Normal	4 (33)	1 (8)	5 (42)	10 (28)	14 (15)
		Missing	1 (8)	1 (8)	1 (8)	3 (8)	6 (6)
	Day 2	Abnormal (not CS)	1 (8)	3 (25)	2 (17)	6 (17)	18 (19)
		Normal	2 (17)	1 (8)	4 (33)	7 (19)	10 (10)
		Missing	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
	Day 8	Abnormal (not CS)	1 (8)	2 (17)	4 (33)	7 (19)	18 (19)
		Normal	2 (17)	4 (33)	4 (33)	10 (28)	12 (13)
		Missing	0 (0)	0 (0)	2 (17)	2 (6)	5 (5)
	Day 29	Abnormal (not CS)	0 (0)	2 (17)	2 (17)	4 (11)	14 (15)
		Normal	1 (8)	3 (25)	5 (42)	9 (25)	12 (13)
		Missing	1 (8)	0 (0)	2 (17)	3 (8)	7 (7)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 17 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Bacteria [/HPF]	Day 50	Abnormal (not CS)	0 (0)	2 (17)	1 (8)	3 (8)	12 (13)
		Normal	3 (25)	3 (25)	4 (33)	10 (28)	12 (13)
		Missing	1 (8)	1 (8)	3 (25)	5 (14)	7 (7)
Bilirubin (Urine) [µmol/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	3 (8)	9 (9)
		Normal	11 (92)	11 (92)	11 (92)	33 (92)	87 (91)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	6 (6)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	90 (94)
	Day 2	CS abnormal	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	92 (96)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	7 (7)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	89 (93)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	89 (93)
	Day 50	Abnormal (not CS)	1 (8)	1 (8)	2 (17)	4 (11)	10 (10)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

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Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Bilirubin (Urine) [µmol/L]	Day 50	Normal	9 (75)	10 (83)	10 (83)	29 (81)	82 (85)
Casts [/HPF]	Day -30 to 0	Normal	1 (8)	5 (42)	5 (42)	11 (31)	29 (30)
		Missing	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)
	Day 1	Normal	5 (42)	2 (17)	8 (67)	15 (42)	29 (30)
		Missing	1 (8)	1 (8)	1 (8)	3 (8)	6 (6)
	Day 2	Normal	3 (25)	4 (33)	6 (50)	13 (36)	27 (28)
		Missing	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
	Day 8	Normal	3 (25)	6 (50)	8 (67)	17 (47)	28 (29)
		Missing	0 (0)	0 (0)	2 (17)	2 (6)	7 (7)
	Day 29	Normal	1 (8)	5 (42)	6 (50)	12 (33)	23 (24)
		Missing	1 (8)	0 (0)	3 (25)	4 (11)	10 (10)
	Day 50	Normal	3 (25)	5 (42)	5 (42)	13 (36)	22 (23)
		Missing	1 (8)	1 (8)	3 (25)	5 (14)	9 (9)
Crystals [/HPF]	Day -30 to 0	Abnormal (not CS)	0 (0)	2 (17)	3 (25)	5 (14)	11 (11)
		Normal	1 (8)	3 (25)	4 (33)	8 (22)	22 (23)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 19 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Crystals [/HPF]	Day 1	Abnormal (not CS)	2 (17)	1 (8)	3 (25)	6 (17)	12 (13)
		Normal	4 (33)	2 (17)	6 (50)	12 (33)	22 (23)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 2	Abnormal (not CS)	1 (8)	0 (0)	2 (17)	3 (8)	6 (6)
		Normal	2 (17)	4 (33)	5 (42)	11 (31)	24 (25)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 8	Abnormal (not CS)	0 (0)	1 (8)	3 (25)	4 (11)	8 (8)
		Normal	3 (25)	5 (42)	7 (58)	15 (42)	25 (26)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
	Day 29	Abnormal (not CS)	1 (8)	1 (8)	2 (17)	4 (11)	11 (11)
		Normal	1 (8)	4 (33)	6 (50)	11 (31)	19 (20)
		Missing	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
	Day 50	Abnormal (not CS)	1 (8)	1 (8)	4 (33)	6 (17)	12 (13)
		Normal	3 (25)	5 (42)	4 (33)	12 (33)	17 (18)
		Missing	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 20 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Epithelial Cells [/HPF]	Day -30 to 0	Abnormal (not CS)	0 (0)	1 (8)	2 (17)	3 (8)	15 (16)
		Normal	1 (8)	4 (33)	3 (25)	8 (22)	14 (15)
		Missing	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	3 (25)	4 (11)	11 (11)
		Normal	4 (33)	2 (17)	5 (42)	11 (31)	19 (20)
		Missing	1 (8)	1 (8)	1 (8)	3 (8)	5 (5)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
		Normal	3 (25)	4 (33)	6 (50)	13 (36)	23 (24)
		Missing	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
	Day 8	Abnormal (not CS)	1 (8)	2 (17)	1 (8)	4 (11)	11 (11)
		Normal	2 (17)	4 (33)	7 (58)	13 (36)	18 (19)
		Missing	0 (0)	0 (0)	2 (17)	2 (6)	6 (6)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	7 (7)
		Normal	1 (8)	5 (42)	5 (42)	11 (31)	17 (18)
		Missing	1 (8)	0 (0)	3 (25)	4 (11)	9 (9)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

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Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Epithelial Cells [/HPF]	Day 50	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (6)	5 (5)
		Normal	3 (25)	4 (33)	4 (33)	11 (31)	17 (18)
		Missing	1 (8)	1 (8)	3 (25)	5 (14)	9 (9)
Erythrocytes (Urine) [/HPF]	Day -30 to 0	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	3 (3)
		Normal	0 (0)	5 (42)	5 (42)	10 (28)	26 (27)
		Missing	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	4 (33)	5 (14)	11 (11)
		Normal	4 (33)	2 (17)	4 (33)	10 (28)	19 (20)
		Missing	1 (8)	1 (8)	1 (8)	3 (8)	5 (5)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
		Normal	3 (25)	4 (33)	6 (50)	13 (36)	22 (23)
		Missing	0 (0)	0 (0)	1 (8)	1 (3)	3 (3)
	Day 8	Abnormal (not CS)	0 (0)	3 (25)	3 (25)	6 (17)	7 (7)
		Normal	3 (25)	3 (25)	5 (42)	11 (31)	21 (22)
		Missing	0 (0)	0 (0)	2 (17)	2 (6)	7 (7)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 22 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Erythrocytes (Urine) [/HPF]	Day 29	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	5 (5)
		Normal	0 (0)	5 (42)	5 (42)	10 (28)	18 (19)
		Missing	1 (8)	0 (0)	3 (25)	4 (11)	10 (10)
	Day 50	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	3 (8)	3 (3)
		Normal	2 (17)	4 (33)	4 (33)	10 (28)	19 (20)
		Missing	1 (8)	1 (8)	3 (25)	5 (14)	9 (9)
Glucose (Urine)	Day -30 to 0	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 1	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 2	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 8	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 29	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 50	Normal	10 (83)	11 (92)	12 (100)	33 (92)	92 (96)
Hemoglobin (Urine) [10^6/L]	Day -30 to 0	Abnormal (not CS)	1 (8)	1 (8)	6 (50)	8 (22)	12 (13)
		Normal	11 (92)	11 (92)	6 (50)	28 (78)	84 (88)
	Day 1	Abnormal (not CS)	4 (33)	1 (8)	9 (75)	14 (39)	27 (28)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 23 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Hemoglobin (Urine) [10^6/L]	Day 1	Normal	8 (67)	11 (92)	3 (25)	22 (61)	69 (72)
	Day 2	CS abnormal	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
		Abnormal (not CS)	3 (25)	3 (25)	6 (50)	12 (33)	24 (25)
		Normal	9 (75)	9 (75)	5 (42)	23 (64)	71 (74)
	Day 8	Abnormal (not CS)	2 (17)	3 (25)	8 (67)	13 (36)	22 (23)
		Normal	10 (83)	9 (75)	4 (33)	23 (64)	74 (77)
	Day 29	Abnormal (not CS)	1 (8)	4 (33)	6 (50)	11 (31)	23 (24)
		Normal	11 (92)	8 (67)	6 (50)	25 (69)	73 (76)
	Day 50	Abnormal (not CS)	3 (25)	5 (42)	8 (67)	16 (44)	21 (22)
		Normal	7 (58)	6 (50)	4 (33)	17 (47)	71 (74)
Ketones [mmol/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	93 (97)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 24 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Ketones [mmol/L]	Day 2	Normal	12 (100)	12 (100)	11 (92)	35 (97)	92 (96)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	5 (5)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	91 (95)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	7 (7)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	89 (93)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
		Normal	10 (83)	11 (92)	12 (100)	33 (92)	86 (90)
Leukocytes (Urine - Dipstick) [10^6/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	3 (25)	3 (25)	6 (17)	20 (21)
		Normal	12 (100)	9 (75)	9 (75)	30 (83)	76 (79)
	Day 1	Abnormal (not CS)	3 (25)	3 (25)	4 (33)	10 (28)	18 (19)
		Normal	9 (75)	9 (75)	8 (67)	26 (72)	78 (81)
	Day 2	CS abnormal	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
		Abnormal (not CS)	1 (8)	2 (17)	2 (17)	5 (14)	14 (15)
		Normal	11 (92)	10 (83)	9 (75)	30 (83)	81 (84)
	Day 8	Abnormal (not CS)	2 (17)	3 (25)	7 (58)	12 (33)	23 (24)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 25 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Leukocytes (Urine - Dipstick) [10^6/L]	Day 8	Normal	10 (83)	9 (75)	5 (42)	24 (67)	73 (76)
	Day 29	Abnormal (not CS)	1 (8)	3 (25)	7 (58)	11 (31)	21 (22)
		Normal	11 (92)	9 (75)	5 (42)	25 (69)	75 (78)
	Day 50	Abnormal (not CS)	1 (8)	3 (25)	4 (33)	8 (22)	18 (19)
		Normal	9 (75)	8 (67)	8 (67)	25 (69)	74 (77)
Leukocytes (Urine - Microscopy) [/HPF]	Day -30 to 0	Abnormal (not CS)	0 (0)	2 (17)	3 (25)	5 (14)	14 (15)
		Normal	1 (8)	3 (25)	2 (17)	6 (17)	15 (16)
		Missing	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)
	Day 1	Abnormal (not CS)	2 (17)	1 (8)	3 (25)	6 (17)	8 (8)
		Normal	3 (25)	1 (8)	5 (42)	9 (25)	21 (22)
		Missing	1 (8)	1 (8)	1 (8)	3 (8)	6 (6)
	Day 2	CS abnormal	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
		Abnormal (not CS)	1 (8)	2 (17)	2 (17)	5 (14)	10 (10)
		Normal	2 (17)	2 (17)	3 (25)	7 (19)	16 (17)
		Missing	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 26 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Leukocytes (Urine - Microscopy) [/HPF]	Day 8	Abnormal (not CS)	1 (8)	3 (25)	5 (42)	9 (25)	16 (17)
		Normal	2 (17)	3 (25)	3 (25)	8 (22)	12 (13)
		Missing	0 (0)	0 (0)	2 (17)	2 (6)	7 (7)
	Day 29	Abnormal (not CS)	0 (0)	2 (17)	3 (25)	5 (14)	9 (9)
		Normal	1 (8)	3 (25)	3 (25)	7 (19)	15 (16)
		Missing	1 (8)	0 (0)	3 (25)	4 (11)	9 (9)
	Day 50	Abnormal (not CS)	0 (0)	2 (17)	2 (17)	4 (11)	7 (7)
		Normal	3 (25)	3 (25)	3 (25)	9 (25)	15 (16)
		Missing	1 (8)	1 (8)	3 (25)	5 (14)	9 (9)
Nitrite	Day -30 to 0	Abnormal (not CS)	0 (0)	2 (17)	1 (8)	3 (8)	5 (5)
		Normal	12 (100)	10 (83)	11 (92)	33 (92)	91 (95)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	94 (98)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	5 (5)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	91 (95)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 27 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Nitrite	Day 8	Abnormal (not CS)	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)
		Normal	12 (100)	12 (100)	10 (83)	34 (94)	92 (96)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	2 (2)
		Normal	12 (100)	12 (100)	11 (92)	35 (97)	94 (98)
	Day 50	Abnormal (not CS)	0 (0)	1 (8)	1 (8)	2 (6)	6 (6)
		Normal	10 (83)	10 (83)	11 (92)	31 (86)	86 (90)
pH	Day -30 to 0	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	4 (4)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	92 (96)
	Day 1	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (6)	8 (8)
		Normal	11 (92)	11 (92)	12 (100)	34 (94)	88 (92)
	Day 2	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	4 (4)
		Normal	12 (100)	11 (92)	12 (100)	35 (97)	92 (96)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	4 (4)
		Normal	11 (92)	12 (100)	11 (92)	34 (94)	92 (96)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 28 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
pH	Day 29	Normal	12 (100)	12 (100)	12 (100)	36 (100)	93 (97)
	Day 50	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	10 (83)	11 (92)	12 (100)	33 (92)	90 (94)
Protein [mg/L]	Day -30 to 0	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	92 (96)
	Day 1	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	4 (4)
		Normal	12 (100)	11 (92)	12 (100)	35 (97)	92 (96)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	93 (97)
	Day 8	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	90 (94)
	Day 50	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
		Normal	9 (75)	11 (92)	12 (100)	32 (89)	90 (94)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 29 of 32)

Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Round Epithelial Cells [/HPF]	Day -30 to 0	Abnormal (not CS)	0 (0)	3 (25)	3 (25)	6 (17)	8 (8)
		Normal	1 (8)	2 (17)	2 (17)	5 (14)	21 (22)
		Missing	0 (0)	0 (0)	2 (17)	2 (6)	4 (4)
	Day 1	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	6 (6)
		Normal	4 (33)	2 (17)	7 (58)	13 (36)	23 (24)
		Missing	1 (8)	1 (8)	1 (8)	3 (8)	6 (6)
	Day 2	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (6)	6 (6)
		Normal	2 (17)	3 (25)	6 (50)	11 (31)	21 (22)
		Missing	0 (0)	0 (0)	1 (8)	1 (3)	4 (4)
	Day 8	Abnormal (not CS)	1 (8)	2 (17)	0 (0)	3 (8)	5 (5)
		Normal	2 (17)	4 (33)	8 (67)	14 (39)	23 (24)
		Missing	0 (0)	0 (0)	2 (17)	2 (6)	7 (7)
	Day 29	Abnormal (not CS)	0 (0)	2 (17)	1 (8)	3 (8)	6 (6)
		Normal	1 (8)	3 (25)	5 (42)	9 (25)	18 (19)
		Missing	1 (8)	0 (0)	3 (25)	4 (11)	9 (9)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

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Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Round Epithelial Cells [/HPF]	Day 50	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
		Normal	3 (25)	4 (33)	5 (42)	12 (33)	21 (22)
		Missing	1 (8)	1 (8)	3 (25)	5 (14)	9 (9)
Specific Gravity	Day -30 to 0	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	2 (6)	7 (7)
		Normal	12 (100)	10 (83)	12 (100)	34 (94)	89 (93)
	Day 1	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
	Day 2	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	95 (99)
	Day 8	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
		Normal	11 (92)	12 (100)	12 (100)	35 (97)	95 (99)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
	Day 50	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
		Normal	10 (83)	10 (83)	12 (100)	32 (89)	91 (95)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

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Table 14.3.2-2.5.3-3: Laboratory: Abnormal and clinically significant values per visit (Urinalysis) - BNT162b2

Safety set

			Older dose ranging cohorts				
Parameter [Unit]	Visit		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Urobilinogen [µmol/L]	Day -30 to 0	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 1	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 2	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 8	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 29	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Normal	12 (100)	12 (100)	12 (100)	36 (100)	95 (99)
	Day 50	Normal	10 (83)	11 (92)	12 (100)	33 (92)	92 (96)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with data available.

Program: Tfsaf_LB_2_5.sas (Page 32 of 32)

14.3.2-3 Vital signs

Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Diastolic Blood Pressure [mmHg]	Day -30 to 0		n	12	12	12	12	12	60
			Mean (SD)	70.4 (10.4)	71.1 (6.9)	68.6 (7.3)	69.8 (12.7)	78.0 (9.7)	71.6 (9.9)
			Min	59	64	54	52	64	52
			Median	69.5	68.5	67.5	69.0	77.5	70.0
			Max	96	87	80	88	93	96
	Day 1	Predose	n	12	12	12	12	12	60
			Mean (SD)	67.7 (7.9)	65.3 (8.0)	64.4 (6.6)	68.8 (11.3)	75.7 (8.6)	68.4 (9.2)
			Min	58	55	54	54	62	54
			Median	66.0	63.0	64.0	66.0	76.0	66.5
			Max	85	82	81	84	87	87
		1 hour	n	12	12	12	12	12	60
			Mean (SD)	69.4 (13.0)	65.4 (7.1)	65.3 (10.3)	67.3 (11.2)	77.2 (6.5)	68.9 (10.6)
			Min	60	58	53	48	67	48
			Median	64.5	64.0	62.0	67.5	76.5	66.5
			Max	104	85	89	89	91	104

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Diastolic Blood Pressure [mmHg]	Day 1	3 hours	n	12	12	12	12	12	60
			Mean (SD)	63.8 (7.7)	62.7 (5.9)	62.3 (11.3)	61.3 (11.8)	71.0 (10.0)	64.2 (9.9)
			Min	57	54	51	40	54	40
			Median	60.5	62.5	59.0	62.0	70.0	62.0
			Max	80	72	92	83	89	92
		6 hours	n	12	12	12	12	12	60
			Mean (SD)	65.8 (7.7)	62.8 (7.2)	64.5 (8.8)	63.4 (12.9)	76.2 (8.6)	66.5 (10.2)
			Min	56	54	55	38	65	38
			Median	66.0	61.0	62.5	64.5	75.5	66.5
			Max	82	79	85	80	95	95
	Day 2		n	12	12	12	12	12	60
			Mean (SD)	69.7 (7.8)	64.6 (7.1)	64.8 (8.7)	68.0 (13.1)	75.6 (9.1)	68.5 (9.9)
			Min	60	58	52	47	66	47
			Median	70.0	62.5	63.0	64.5	73.5	66.5
			Max	85	80	88	94	94	94

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Diastolic Blood Pressure [mmHg]	Day 8		n	12	12	12	12	12	60
			Mean (SD)	67.3 (8.5)	65.3 (5.9)	64.6 (7.8)	65.5 (14.7)	77.1 (8.6)	68.0 (10.4)
			Min	55	54	50	32	65	32
			Median	65.0	63.5	65.0	67.5	75.0	67.5
			Max	86	77	79	89	93	93
	Day 22	Predose	n	11	12	11	12	12	58
			Mean (SD)	67.8 (7.3)	65.0 (7.3)	64.5 (7.5)	67.8 (10.7)	75.2 (9.6)	68.1 (9.2)
			Min	56	56	55	50	64	50
			Median	68.0	62.5	64.0	65.0	72.5	67.0
			Max	80	80	79	84	95	95
		1 hour	n	11	12	11	12	12	58
			Mean (SD)	66.9 (7.8)	65.0 (8.1)	66.5 (6.5)	65.8 (11.8)	75.6 (9.1)	68.0 (9.4)
			Min	56	54	58	41	66	41
			Median	66.0	61.5	64.0	64.5	73.5	66.5
			Max	81	81	78	83	93	93

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Diastolic Blood Pressure [mmHg]	Day 22	3 hours	n	11	12	11	12	12	58
			Mean (SD)	63.8 (5.3)	62.8 (6.4)	62.9 (9.0)	63.8 (12.2)	72.1 (8.8)	65.1 (9.1)
			Min	58	55	46	38	61	38
			Median	62.0	60.5	61.0	67.5	69.5	64.5
			Max	76	77	76	79	90	90
		6 hours	n	11	12	11	12	12	58
			Mean (SD)	64.7 (7.7)	64.2 (7.9)	62.4 (9.2)	61.5 (12.7)	74.2 (8.6)	65.4 (10.2)
			Min	49	53	49	45	62	45
			Median	66.0	61.0	61.0	59.0	71.5	64.5
			Max	76	77	84	84	92	92
		Missing	n	1	0	0	0	0	1
			Mean (SD)	63.0 (-)	- (-)	- (-)	- (-)	- (-)	63.0 (-)
			Min	63	-	-	-	-	63
			Median	63.0	-	-	-	-	63.0
			Max	63	-	-	-	-	63

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Diastolic Blood Pressure [mmHg]	Day 29		n	12	12	12	12	12	60
			Mean (SD)	67.0 (8.5)	65.6 (8.1)	65.3 (8.6)	63.6 (9.9)	75.8 (7.7)	67.5 (9.4)
			Min	56	50	54	48	65	48
			Median	65.0	66.0	64.0	62.5	73.5	66.5
			Max	80	79	85	84	90	90
	Day 43		n	11	12	11	12	11	57
			Mean (SD)	67.5 (6.7)	67.4 (7.3)	66.2 (8.3)	65.8 (11.1)	75.4 (7.4)	68.4 (8.8)
			Min	56	56	57	46	67	46
			Median	69.0	68.5	64.0	65.0	72.0	69.0
			Max	77	81	87	82	89	89
	Day 50		n	11	12	12	12	12	59
			Mean (SD)	65.4 (7.3)	64.8 (6.8)	65.4 (6.4)	64.8 (11.7)	74.2 (8.5)	66.9 (8.9)
			Min	57	56	53	43	63	43
			Median	63.0	64.0	65.0	66.0	71.0	67.0
			Max	77	78	78	79	90	90

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Diastolic Blood Pressure [mmHg]	Day 85		n	11	10	11	12	12	56
			Mean (SD)	70.6 (6.9)	67.6 (6.9)	65.7 (6.8)	66.2 (12.7)	76.0 (9.5)	69.3 (9.5)
			Min	62	59	53	43	66	43
			Median	71.0	65.5	66.0	69.5	74.0	68.5
			Max	83	79	80	85	94	94
Pulse Rate [beats/min]	Day -30 to 0		n	12	12	12	12	12	60
			Mean (SD)	58.0 (9.5)	62.9 (9.3)	66.5 (8.3)	68.1 (13.5)	65.2 (9.0)	64.1 (10.4)
			Min	43	49	50	47	52	43
			Median	54.0	63.0	67.0	66.5	64.0	64.0
			Max	76	79	78	99	79	99
	Day 1	Predose	n	12	12	12	12	12	60
			Mean (SD)	59.3 (12.7)	67.0 (11.7)	62.3 (6.3)	67.5 (14.6)	66.1 (6.4)	64.4 (11.0)
			Min	47	47	51	50	56	47
			Median	53.5	66.5	63.5	62.5	66.5	63.5
			Max	88	92	70	97	77	97

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Pulse Rate [beats/min]	Day 1	1 hour	n	12	12	12	12	12	60
			Mean (SD)	52.6 (9.6)	56.4 (6.1)	56.3 (6.6)	58.8 (9.8)	59.8 (5.0)	56.8 (7.8)
			Min	43	43	46	43	49	43
			Median	49.0	58.0	56.5	56.5	60.5	57.0
			Max	74	64	67	78	66	78
		3 hours	n	12	12	12	12	12	60
			Mean (SD)	60.4 (11.7)	61.8 (9.1)	66.9 (12.1)	65.6 (8.2)	64.3 (10.0)	63.8 (10.3)
			Min	46	50	46	51	51	46
			Median	59.0	61.5	65.5	65.5	64.5	62.0
			Max	82	81	92	80	79	92
		6 hours	n	12	12	12	12	12	60
			Mean (SD)	59.2 (10.7)	63.8 (9.4)	65.4 (6.7)	68.0 (10.9)	66.3 (9.0)	64.5 (9.6)
			Min	44	48	54	48	53	44
			Median	56.5	65.0	65.0	71.5	67.0	62.5
			Max	80	76	75	80	78	80

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Pulse Rate [beats/min]	Day 2		n	12	12	12	12	12	60
			Mean (SD)	56.9 (9.3)	62.8 (9.6)	67.6 (8.2)	68.3 (9.9)	70.1 (8.6)	65.1 (10.1)
			Min	45	45	51	49	55	45
			Median	54.5	65.0	68.0	69.0	69.5	67.0
			Max	75	75	79	85	86	86
	Day 8		n	12	12	12	12	12	60
			Mean (SD)	61.1 (17.5)	63.6 (7.6)	61.1 (8.1)	66.3 (14.2)	62.1 (5.6)	62.8 (11.3)
			Min	44	50	53	41	55	41
			Median	54.0	62.0	57.5	62.5	60.5	60.0
			Max	95	76	77	89	70	95
	Day 22	Predose	n	11	12	11	12	12	58
			Mean (SD)	58.0 (10.4)	63.9 (9.4)	61.2 (8.3)	69.5 (15.6)	65.4 (7.4)	63.7 (11.0)
			Min	47	49	47	45	52	45
			Median	54.0	64.5	64.0	67.0	66.0	64.5
			Max	80	82	72	96	75	96

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Pulse Rate [beats/min]	Day 22	1 hour	n	11	12	11	12	12	58
			Mean (SD)	51.4 (6.7)	56.5 (6.7)	57.1 (7.0)	60.8 (9.6)	58.3 (7.4)	56.9 (7.9)
			Min	45	46	44	42	46	42
			Median	50.0	56.5	59.0	62.5	58.0	55.5
			Max	69	67	66	73	70	73
		3 hours	n	11	12	11	12	12	58
			Mean (SD)	56.6 (10.9)	60.9 (11.1)	64.3 (8.7)	67.3 (7.8)	65.0 (10.5)	62.9 (10.2)
			Min	42	44	54	54	48	42
			Median	55.0	62.0	62.0	69.0	65.5	62.0
			Max	77	84	83	78	78	84
		6 hours	n	11	12	11	12	12	58
			Mean (SD)	59.0 (6.8)	66.3 (10.0)	68.5 (9.9)	69.8 (9.4)	66.4 (8.3)	66.1 (9.4)
			Min	46	51	55	52	54	46
			Median	58.0	69.5	66.0	73.0	66.0	66.0
			Max	75	80	89	80	79	89

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Pulse Rate [beats/min]	Day 22	Missing	n	1	0	0	0	0	1
			Mean (SD)	76.0 (-)	- (-)	- (-)	- (-)	- (-)	76.0 (-)
			Min	76	-	-	-	-	76
			Median	76.0	-	-	-	-	76.0
			Max	76	-	-	-	-	76
	Day 29		n	12	12	12	12	12	60
			Mean (SD)	57.8 (10.1)	63.6 (10.9)	63.3 (6.4)	65.4 (10.1)	64.0 (9.9)	62.8 (9.7)
			Min	47	46	57	40	50	40
			Median	56.5	61.5	60.0	66.5	66.0	63.0
			Max	78	82	76	75	76	82
	Day 43		n	11	12	11	12	11	57
			Mean (SD)	57.5 (10.1)	66.2 (7.8)	69.0 (11.8)	68.8 (11.0)	68.1 (5.2)	66.0 (10.1)
			Min	44	54	49	45	60	44
			Median	57.0	63.5	74.0	70.0	68.0	65.0
			Max	82	82	84	85	79	85

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Pulse Rate [beats/min]	Day 50		n	11	12	12	12	12	59
			Mean (SD)	56.5 (8.3)	63.5 (9.6)	65.5 (8.7)	64.8 (10.6)	67.5 (9.4)	63.7 (9.8)
			Min	44	50	47	43	53	43
			Median	58.0	64.0	65.5	66.5	68.0	63.0
			Max	75	81	79	80	85	85
	Day 85		n	11	10	11	12	12	56
			Mean (SD)	61.6 (9.3)	65.1 (7.4)	64.0 (8.7)	66.7 (14.0)	70.6 (9.7)	65.7 (10.3)
			Min	49	52	50	45	52	45
			Median	62.0	66.0	65.0	64.5	71.0	65.0
			Max	82	79	79	90	83	90
Respiratory Rate [breaths/min]	Day -30 to 0		n	12	12	12	12	12	60
			Mean (SD)	15.8 (3.1)	15.3 (2.4)	13.9 (2.7)	16.5 (4.3)	14.4 (3.3)	15.2 (3.2)
			Min	11	11	9	8	8	8
			Median	16.5	15.5	15.0	18.5	16.0	16.0
			Max	20	20	17	20	20	20

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Respiratory Rate [breaths/min]	Day 1	Predose	n	12	12	12	12	12	60
			Mean (SD)	15.7 (3.0)	15.5 (3.1)	14.9 (2.8)	14.0 (3.1)	12.8 (2.5)	14.6 (3.0)
			Min	9	10	9	8	9	8
			Median	16.0	15.5	16.0	15.5	13.5	15.0
			Max	20	19	19	17	17	20
		1 hour	n	12	12	12	12	12	60
			Mean (SD)	15.3 (2.7)	14.8 (2.4)	15.0 (2.2)	15.3 (3.1)	13.7 (2.6)	14.8 (2.6)
			Min	10	11	11	8	10	8
			Median	15.0	14.5	14.5	16.0	14.0	15.0
			Max	20	20	19	19	18	20
		3 hours	n	12	12	12	12	12	60
			Mean (SD)	14.8 (2.4)	15.2 (3.2)	15.7 (2.2)	15.7 (2.5)	14.6 (2.2)	15.2 (2.5)
			Min	10	8	11	10	11	8
			Median	14.5	16.0	15.5	16.0	15.5	16.0
			Max	18	20	20	20	18	20

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Respiratory Rate [breaths/min]	Day 1	6 hours	n	12	12	12	12	12	60
			Mean (SD)	16.3 (2.2)	16.1 (2.5)	14.1 (2.8)	16.0 (3.3)	14.7 (2.9)	15.4 (2.8)
			Min	11	11	11	9	10	9
			Median	17.0	16.0	13.5	16.0	14.5	16.0
			Max	19	20	19	20	19	20
	Day 2		n	12	12	12	12	12	60
			Mean (SD)	14.7 (2.8)	14.4 (2.7)	15.4 (3.1)	15.3 (3.4)	14.9 (3.0)	15.0 (2.9)
			Min	9	9	10	9	9	9
			Median	15.0	14.5	16.0	16.0	16.0	15.5
			Max	18	20	20	20	18	20
	Day 8		n	12	12	12	12	12	60
			Mean (SD)	15.0 (3.0)	14.9 (4.0)	15.6 (2.4)	16.1 (3.3)	13.6 (3.6)	15.0 (3.3)
			Min	9	8	11	10	8	8
			Median	15.5	14.0	15.5	18.0	14.0	16.0
			Max	19	20	19	19	19	20

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Respiratory Rate [breaths/min]	Day 22	Predose	n	11	12	11	12	12	58
			Mean (SD)	15.3 (3.3)	14.3 (2.2)	14.5 (2.2)	14.3 (3.7)	14.1 (2.8)	14.5 (2.8)
			Min	8	10	11	8	10	8
			Median	16.0	14.0	15.0	15.0	14.5	15.0
			Max	18	17	18	19	18	19
		1 hour	n	11	12	11	12	12	58
			Mean (SD)	14.6 (1.9)	14.6 (3.5)	15.4 (2.5)	14.6 (3.7)	14.7 (2.9)	14.8 (2.9)
			Min	11	8	10	8	10	8
			Median	15.0	15.5	16.0	15.0	15.0	15.0
			Max	17	18	19	19	18	19
		3 hours	n	11	12	11	12	12	58
			Mean (SD)	15.5 (3.0)	14.8 (2.7)	16.3 (2.7)	14.8 (3.1)	16.2 (1.8)	15.5 (2.7)
			Min	9	10	11	9	13	9
			Median	16.0	15.5	16.0	15.0	16.5	16.0
			Max	19	18	20	20	19	20

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Respiratory Rate [breaths/min]	Day 22	6 hours	n	11	12	11	12	12	58
			Mean (SD)	17.3 (3.1)	13.9 (3.7)	15.7 (1.7)	15.8 (3.5)	13.9 (2.1)	15.3 (3.1)
			Min	11	9	13	11	11	9
			Median	19.0	12.0	16.0	17.0	14.0	15.0
			Max	20	20	18	20	19	20
		Missing	n	1	0	0	0	0	1
			Mean (SD)	17.0 (-)	- (-)	- (-)	- (-)	- (-)	17.0 (-)
			Min	17	-	-	-	-	17
			Median	17.0	-	-	-	-	17.0
			Max	17	-	-	-	-	17
	Day 29		n	12	12	12	12	12	60
			Mean (SD)	16.1 (3.1)	14.6 (3.3)	14.1 (3.4)	16.1 (3.9)	13.5 (4.0)	14.9 (3.6)
			Min	9	9	10	9	8	8
			Median	16.5	15.5	13.0	18.0	12.5	16.0
			Max	20	19	19	20	19	20

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Respiratory Rate [breaths/min]	Day 43		n	11	12	11	12	11	57
			Mean (SD)	14.2 (3.7)	14.8 (2.4)	15.2 (3.1)	15.3 (4.3)	15.1 (4.2)	14.9 (3.5)
			Min	10	12	10	9	8	8
			Median	14.0	14.0	16.0	17.0	16.0	16.0
			Max	19	20	19	20	20	20
	Day 50		n	11	12	12	12	12	59
			Mean (SD)	14.7 (3.7)	14.0 (3.5)	15.4 (3.2)	14.2 (4.2)	15.5 (3.0)	14.8 (3.5)
			Min	8	9	10	8	11	8
			Median	16.0	14.0	16.5	14.5	16.0	15.0
			Max	20	19	20	19	19	20
	Day 85		n	11	10	11	12	12	56
			Mean (SD)	15.6 (3.1)	16.3 (2.7)	14.1 (3.0)	15.3 (3.7)	14.5 (3.3)	15.1 (3.2)
			Min	11	12	9	9	10	9
			Median	17.0	15.5	14.0	15.5	14.0	15.0
			Max	20	20	18	20	20	20

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Systolic Blood Pressure [mmHg]	Day -30 to 0		n	12	12	12	12	12	60
			Mean (SD)	119.1 (9.4)	121.1 (10.7)	118.4 (11.7)	115.8 (13.0)	127.8 (10.6)	120.5 (11.5)
			Min	104	107	100	100	114	100
			Median	119.0	118.0	117.0	112.0	127.5	119.0
			Max	139	142	136	141	147	147
	Day 1	Predose	n	12	12	12	12	12	60
			Mean (SD)	119.6 (10.4)	118.3 (10.1)	111.4 (13.8)	118.2 (14.0)	127.8 (10.5)	119.0 (12.6)
			Min	106	102	94	99	114	94
			Median	120.0	118.0	107.5	120.5	127.5	119.5
			Max	139	132	139	145	148	148
		1 hour	n	12	12	12	12	12	60
			Mean (SD)	116.5 (11.4)	113.2 (13.1)	111.1 (10.9)	115.5 (9.6)	127.0 (10.8)	116.7 (12.1)
			Min	104	97	98	102	108	97
			Median	115.5	111.5	109.5	115.0	123.5	116.0
			Max	144	147	131	137	145	147

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Systolic Blood Pressure [mmHg]	Day 1	3 hours	n	12	12	12	12	12	60
			Mean (SD)	118.2 (8.0)	113.7 (8.6)	113.8 (19.1)	112.3 (8.2)	124.3 (13.1)	116.5 (12.6)
			Min	107	99	94	101	106	94
			Median	118.0	113.0	111.0	110.5	127.0	115.0
			Max	135	127	167	131	147	167
		6 hours	n	12	12	12	12	12	60
			Mean (SD)	115.6 (8.7)	116.0 (10.8)	118.1 (14.4)	114.3 (11.8)	130.7 (9.0)	118.9 (12.3)
			Min	105	102	100	102	114	100
			Median	112.0	115.0	113.0	110.5	130.0	116.0
			Max	135	132	151	137	142	151
	Day 2		n	12	12	12	12	12	60
			Mean (SD)	115.6 (8.3)	114.8 (9.6)	113.3 (15.0)	115.9 (12.9)	124.3 (9.0)	116.8 (11.5)
			Min	98	99	95	104	108	95
			Median	114.5	115.0	110.0	112.5	123.5	115.0
			Max	127	131	149	149	139	149

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Systolic Blood Pressure [mmHg]	Day 8		n	12	12	12	12	12	60
			Mean (SD)	113.7 (6.2)	115.7 (12.0)	113.3 (11.4)	114.4 (13.1)	127.1 (9.2)	116.8 (11.6)
			Min	105	103	98	99	115	98
			Median	114.5	112.0	111.5	115.0	124.0	115.5
			Max	125	137	130	138	142	142
	Day 22	Predose	n	11	12	11	12	12	58
			Mean (SD)	115.8 (6.9)	114.9 (11.0)	113.1 (8.9)	113.7 (11.5)	124.8 (8.5)	116.5 (10.2)
			Min	103	95	97	98	115	95
			Median	115.0	115.0	111.0	109.0	122.0	115.0
			Max	131	133	130	132	142	142
		1 hour	n	11	12	11	12	12	58
			Mean (SD)	113.4 (8.3)	114.3 (9.8)	115.1 (8.7)	113.7 (12.8)	125.0 (10.6)	116.4 (10.8)
			Min	103	101	102	98	109	98
			Median	113.0	111.0	116.0	111.5	122.5	115.0
			Max	135	130	128	136	148	148

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Systolic Blood Pressure [mmHg]	Day 22	3 hours	n	11	12	11	12	12	58
			Mean (SD)	115.1 (10.9)	116.9 (12.4)	116.0 (14.3)	115.3 (13.9)	120.9 (8.7)	116.9 (12.0)
			Min	105	102	100	99	108	99
			Median	113.0	115.0	112.0	110.5	118.5	114.5
			Max	142	137	143	137	137	143
		6 hours	n	11	12	11	12	12	58
			Mean (SD)	115.6 (8.5)	118.0 (9.6)	120.1 (12.7)	110.9 (13.1)	127.0 (11.3)	118.3 (12.1)
			Min	102	105	107	94	110	94
			Median	116.0	119.0	116.0	107.5	131.5	116.5
			Max	135	132	142	140	144	144
		Missing	n	1	0	0	0	0	1
			Mean (SD)	113.0 (-)	- (-)	- (-)	- (-)	- (-)	113.0 (-)
			Min	113	-	-	-	-	113
			Median	113.0	-	-	-	-	113.0
			Max	113	-	-	-	-	113

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Systolic Blood Pressure [mmHg]	Day 29		n	12	12	12	12	12	60
			Mean (SD)	114.5 (7.3)	116.7 (9.9)	111.8 (9.4)	111.0 (9.3)	125.2 (8.7)	115.8 (10.1)
			Min	99	97	100	101	109	97
			Median	114.5	116.0	110.5	109.0	125.5	115.0
			Max	124	135	131	133	140	140
	Day 43		n	11	12	11	12	11	57
			Mean (SD)	116.7 (10.1)	116.9 (9.7)	113.5 (6.6)	113.6 (10.2)	125.3 (11.0)	117.1 (10.2)
			Min	101	104	106	99	112	99
			Median	117.0	117.0	113.0	112.0	124.0	117.0
			Max	134	137	126	130	150	150
	Day 50		n	11	12	12	12	12	59
			Mean (SD)	116.2 (6.9)	117.6 (9.9)	110.5 (11.3)	112.0 (11.7)	123.9 (10.4)	116.0 (11.0)
			Min	103	105	85	86	114	85
			Median	115.0	115.0	111.0	111.0	121.5	115.0
			Max	130	134	123	131	150	150

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Systolic Blood Pressure [mmHg]	Day 85		n	11	10	11	12	12	56
			Mean (SD)	120.6 (9.4)	120.3 (12.4)	115.1 (10.2)	114.8 (13.9)	127.3 (12.6)	119.7 (12.4)
			Min	105	107	100	94	112	94
			Median	118.0	117.5	114.0	113.0	128.0	117.5
			Max	135	140	138	140	155	155
Temperature [°C]	Day -30 to 0		n	12	12	12	12	12	60
			Mean (SD)	36.18 (0.35)	36.42 (0.30)	36.42 (0.28)	36.25 (0.17)	36.29 (0.25)	36.31 (0.28)
			Min	35.6	36.0	36.0	36.0	35.8	35.6
			Median	36.20	36.40	36.50	36.25	36.35	36.30
			Max	36.7	36.9	36.8	36.6	36.6	36.9
	Day 1	Predose	n	12	12	12	12	12	60
			Mean (SD)	36.21 (0.35)	36.51 (0.29)	36.20 (0.30)	36.36 (0.47)	36.19 (0.26)	36.29 (0.35)
			Min	35.7	35.9	35.5	35.7	35.7	35.5
			Median	36.30	36.50	36.25	36.40	36.10	36.30
			Max	36.6	36.9	36.6	37.2	36.7	37.2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Temperature [°C]	Day 1	1 hour	n	12	12	12	12	12	60
			Mean (SD)	36.10 (0.34)	36.28 (0.27)	36.24 (0.24)	36.44 (0.37)	35.98 (0.27)	36.21 (0.33)
			Min	35.7	35.8	35.9	35.7	35.6	35.6
			Median	36.10	36.35	36.30	36.50	35.90	36.20
			Max	36.7	36.6	36.7	36.9	36.5	36.9
		3 hours	n	12	12	12	12	12	60
			Mean (SD)	36.35 (0.25)	36.40 (0.24)	36.39 (0.33)	36.38 (0.26)	36.13 (0.37)	36.33 (0.30)
			Min	35.7	36.1	35.9	35.9	35.3	35.3
			Median	36.40	36.30	36.50	36.35	36.25	36.30
			Max	36.6	36.9	36.9	36.8	36.7	36.9
		6 hours	n	12	12	12	12	12	60
			Mean (SD)	36.41 (0.34)	36.58 (0.24)	36.48 (0.43)	36.65 (0.25)	36.23 (0.26)	36.47 (0.34)
			Min	35.8	36.3	35.6	36.1	35.8	35.6
			Median	36.45	36.55	36.50	36.65	36.20	36.50
			Max	36.9	36.9	37.0	36.9	36.6	37.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Temperature [°C]	Day 2		n	12	12	12	12	12	60
			Mean (SD)	36.16 (0.28)	36.29 (0.29)	36.46 (0.25)	36.35 (0.26)	36.45 (0.38)	36.34 (0.31)
			Min	35.8	35.7	36.1	35.9	35.7	35.7
			Median	36.15	36.35	36.50	36.35	36.50	36.30
			Max	36.7	36.8	36.8	36.9	37.1	37.1
	Day 8		n	12	12	12	12	12	60
			Mean (SD)	36.12 (0.30)	36.25 (0.28)	36.28 (0.46)	36.37 (0.31)	36.06 (0.33)	36.22 (0.35)
			Min	35.7	35.9	35.8	35.8	35.5	35.5
			Median	36.05	36.20	36.25	36.40	36.05	36.20
			Max	36.6	36.9	37.5	36.8	36.6	37.5
	Day 22	Predose	n	11	12	11	12	12	58
			Mean (SD)	36.25 (0.32)	36.34 (0.35)	36.30 (0.37)	36.54 (0.30)	36.20 (0.31)	36.33 (0.34)
			Min	35.8	35.9	35.8	36.1	35.9	35.8
			Median	36.30	36.25	36.10	36.50	36.15	36.25
			Max	36.9	37.0	36.9	37.1	37.0	37.1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Temperature [°C]	Day 22	1 hour	n	11	12	11	12	12	58
			Mean (SD)	36.07 (0.23)	36.21 (0.25)	36.09 (0.33)	36.32 (0.26)	35.87 (0.25)	36.11 (0.30)
			Min	35.7	35.7	35.6	35.7	35.6	35.6
			Median	36.10	36.30	36.20	36.40	35.80	36.15
			Max	36.4	36.5	36.6	36.6	36.5	36.6
		3 hours	n	11	12	11	12	12	58
			Mean (SD)	36.35 (0.19)	36.38 (0.35)	36.35 (0.42)	36.43 (0.36)	36.16 (0.33)	36.33 (0.34)
			Min	36.1	35.9	35.7	35.7	35.7	35.7
			Median	36.30	36.45	36.50	36.45	36.10	36.30
			Max	36.6	36.9	37.0	37.0	36.9	37.0
		6 hours	n	11	12	11	12	12	58
			Mean (SD)	36.43 (0.30)	36.52 (0.32)	36.59 (0.43)	36.58 (0.27)	36.47 (0.34)	36.52 (0.33)
			Min	35.7	35.9	35.5	36.1	36.0	35.5
			Median	36.50	36.55	36.50	36.50	36.45	36.50
			Max	36.8	37.0	37.0	36.9	37.0	37.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Temperature [°C]	Day 22	Missing	n	1	0	0	0	0	1
			Mean (SD)	36.10 (-)	- (-)	- (-)	- (-)	- (-)	36.10 (-)
			Min	36.1	-	-	-	-	36.1
			Median	36.10	-	-	-	-	36.10
			Max	36.1	-	-	-	-	36.1
	Day 29		n	12	12	12	12	12	60
			Mean (SD)	36.17 (0.31)	36.28 (0.43)	36.33 (0.36)	36.32 (0.37)	36.19 (0.33)	36.26 (0.36)
			Min	35.7	35.7	35.8	35.9	35.8	35.7
			Median	36.15	36.30	36.40	36.30	36.10	36.20
			Max	36.6	37.0	36.9	36.9	36.8	37.0
	Day 43		n	11	12	11	12	11	57
			Mean (SD)	36.05 (0.44)	36.43 (0.29)	36.33 (0.35)	36.53 (0.27)	36.21 (0.34)	36.32 (0.37)
			Min	35.5	35.9	35.8	36.1	35.8	35.5
			Median	36.10	36.50	36.30	36.60	36.10	36.30
			Max	36.8	37.0	36.8	36.9	37.0	37.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12)	3 µg (N=12)	10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=60)
Temperature [°C]	Day 50		n	11	12	12	12	12	59
			Mean (SD)	36.15 (0.34)	36.36 (0.32)	36.23 (0.32)	36.41 (0.12)	36.18 (0.36)	36.26 (0.31)
			Min	35.7	35.6	35.9	36.3	35.9	35.6
			Median	36.10	36.50	36.30	36.40	36.00	36.30
			Max	36.7	36.8	36.8	36.6	37.1	37.1
	Day 85		n	11	9	11	12	12	55
			Mean (SD)	36.11 (0.28)	36.29 (0.46)	36.39 (0.28)	36.40 (0.19)	36.36 (0.36)	36.31 (0.32)
			Min	35.7	35.6	36.0	36.1	35.7	35.6
			Median	36.10	36.40	36.40	36.45	36.50	36.40
			Max	36.5	36.9	36.8	36.7	37.0	37.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Diastolic Blood Pressure [mmHg]	Day -30 to 0		n	12	12	12	36	96
			Mean (SD)	78.6 (11.6)	74.8 (8.6)	76.6 (7.9)	76.7 (9.3)	73.5 (9.9)
			Min	51	65	62	51	51
			Median	80.0	73.5	77.5	78.0	73.0
			Max	95	93	89	95	96
	Day 1	Predose	n	12	12	12	36	96
			Mean (SD)	77.8 (9.7)	73.3 (6.8)	68.8 (7.3)	73.3 (8.7)	70.2 (9.3)
			Min	54	64	58	54	54
			Median	79.5	73.0	69.5	73.0	69.0
			Max	87	87	83	87	87
		1 hour	n	12	12	12	36	96
			Mean (SD)	71.2 (9.0)	72.8 (8.7)	68.1 (6.0)	70.7 (8.0)	69.6 (9.7)
			Min	50	60	58	50	48
			Median	72.0	71.5	68.0	71.0	68.5
			Max	86	90	77	90	104

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Diastolic Blood Pressure [mmHg]	Day 1	3 hours	n	12	12	12	36	96
			Mean (SD)	72.3 (8.1)	71.7 (11.3)	69.1 (6.3)	71.0 (8.7)	66.8 (10.0)
			Min	59	51	60	51	40
			Median	71.0	71.5	71.0	71.5	65.5
			Max	88	85	80	88	92
		6 hours	n	12	12	12	36	96
			Mean (SD)	74.2 (11.4)	70.2 (7.6)	67.8 (5.9)	70.7 (8.8)	68.1 (9.9)
			Min	50	55	55	50	38
			Median	75.5	71.5	69.5	70.0	68.5
			Max	89	81	74	89	95
	Day 2		n	12	12	12	36	96
			Mean (SD)	78.2 (8.4)	71.0 (9.4)	70.3 (8.0)	73.1 (9.1)	70.3 (9.9)
			Min	64	49	57	49	47
			Median	79.0	70.5	71.0	71.0	69.0
			Max	89	83	83	89	94

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Diastolic Blood Pressure [mmHg]	Day 8		n	11	12	12	35	95
			Mean (SD)	80.1 (9.2)	74.4 (8.5)	76.3 (8.3)	76.9 (8.7)	71.2 (10.7)
			Min	60	59	65	59	32
			Median	81.0	75.0	78.0	78.0	71.0
			Max	96	88	88	96	96
	Day 22	Predose	n	12	12	12	36	94
			Mean (SD)	74.4 (12.8)	71.2 (7.5)	78.2 (5.8)	74.6 (9.4)	70.6 (9.7)
			Min	53	55	68	53	50
			Median	76.5	71.5	79.5	76.5	70.0
			Max	89	80	89	89	95
		1 hour	n	12	12	12	36	94
			Mean (SD)	71.9 (11.4)	73.4 (6.5)	70.7 (5.8)	72.0 (8.1)	69.5 (9.1)
			Min	58	66	63	58	41
			Median	71.5	72.0	70.5	72.0	68.5
			Max	98	89	84	98	98

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Diastolic Blood Pressure [mmHg]	Day 22	3 hours	n	12	12	12	36	94
			Mean (SD)	72.8 (10.5)	70.3 (10.3)	71.7 (5.9)	71.6 (8.9)	67.6 (9.5)
			Min	60	55	61	55	38
			Median	73.5	74.0	72.5	73.0	67.0
			Max	88	88	83	88	90
		6 hours	n	12	12	12	36	94
			Mean (SD)	72.3 (12.2)	72.2 (6.6)	72.0 (6.7)	72.2 (8.7)	68.0 (10.1)
			Min	45	62	58	45	45
			Median	74.5	73.0	71.5	72.5	68.5
			Max	93	81	80	93	93
		Missing	n	0	0	0	0	1
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	63.0 (-)
			Min	-	-	-	-	63
			Median	-	-	-	-	63.0
			Max	-	-	-	-	63

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Diastolic Blood Pressure [mmHg]	Day 29		n	12	12	12	36	96
			Mean (SD)	82.8 (9.2)	72.3 (8.9)	78.6 (6.8)	77.9 (9.2)	71.4 (10.6)
			Min	67	55	65	55	48
			Median	82.5	75.0	78.5	78.0	72.0
			Max	96	85	90	96	96
	Day 43		n	12	12	12	36	93
			Mean (SD)	81.1 (9.5)	72.2 (8.3)	78.8 (6.4)	77.4 (8.8)	71.9 (9.8)
			Min	64	60	68	60	46
			Median	84.0	72.0	77.5	77.5	72.0
			Max	92	86	88	92	92
	Day 50		n	12	11	12	35	94
			Mean (SD)	78.5 (10.1)	72.6 (7.6)	77.1 (8.0)	76.2 (8.8)	70.4 (9.9)
			Min	52	64	56	52	43
			Median	79.5	71.0	80.0	79.0	70.0
			Max	92	85	84	92	92

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Diastolic Blood Pressure [mmHg]	Day 85		n	0	0	0	0	56
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	69.3 (9.5)
			Min	-	-	-	-	43
			Median	-	-	-	-	68.5
			Max	-	-	-	-	94
Pulse Rate [beats/min]	Day -30 to 0		n	12	12	12	36	96
			Mean (SD)	61.3 (5.7)	74.6 (8.5)	61.3 (6.9)	65.8 (9.4)	64.7 (10.0)
			Min	52	65	50	50	43
			Median	62.0	73.0	60.5	65.0	64.0
			Max	69	94	74	94	99
	Day 1	Predose	n	12	12	12	36	96
			Mean (SD)	61.3 (4.0)	69.8 (12.5)	64.8 (8.4)	65.3 (9.4)	64.8 (10.4)
			Min	56	51	51	51	47
			Median	60.0	68.5	64.0	62.0	63.0
			Max	71	97	78	97	97

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Pulse Rate [beats/min]	Day 1	1 hour	n	12	12	12	36	96
			Mean (SD)	63.3 (8.7)	61.0 (8.7)	69.9 (9.7)	64.7 (9.6)	59.8 (9.3)
			Min	54	52	58	52	43
			Median	62.5	59.0	68.0	64.0	59.0
			Max	85	79	86	86	86
		3 hours	n	12	12	12	36	96
			Mean (SD)	63.3 (6.7)	66.1 (9.6)	64.8 (10.3)	64.7 (8.8)	64.1 (9.7)
			Min	55	50	45	45	45
			Median	61.0	65.0	63.5	62.5	62.0
			Max	74	83	80	83	92
		6 hours	n	12	12	12	36	96
			Mean (SD)	63.4 (6.6)	67.3 (9.2)	69.4 (9.0)	66.7 (8.5)	65.4 (9.2)
			Min	55	55	51	51	44
			Median	62.5	65.5	69.5	65.5	64.0
			Max	80	86	83	86	86

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Pulse Rate [beats/min]	Day 2		n	12	12	12	36	96
			Mean (SD)	60.8 (4.5)	68.3 (8.0)	71.3 (9.5)	66.8 (8.6)	65.8 (9.5)
			Min	53	52	55	52	45
			Median	61.0	70.0	71.5	66.0	67.0
			Max	67	78	85	85	86
	Day 8		n	11	12	12	35	95
			Mean (SD)	58.5 (7.1)	69.8 (10.2)	62.3 (7.2)	63.7 (9.4)	63.1 (10.6)
			Min	45	53	51	45	41
			Median	59.0	67.0	63.0	64.0	62.0
			Max	70	85	78	85	95
	Day 22	Predose	n	12	12	12	36	94
			Mean (SD)	62.1 (6.6)	69.9 (11.7)	63.9 (7.9)	65.3 (9.4)	64.3 (10.4)
			Min	50	53	53	50	45
			Median	61.5	68.5	64.5	64.0	64.0
			Max	74	87	82	87	96

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Pulse Rate [beats/min]	Day 22	1 hour	n	12	12	12	36	94
			Mean (SD)	66.9 (7.9)	63.1 (7.8)	64.3 (8.9)	64.8 (8.1)	59.9 (8.9)
			Min	55	51	51	51	42
			Median	67.0	61.5	64.5	64.5	60.0
			Max	80	76	85	85	85
		3 hours	n	12	12	12	36	94
			Mean (SD)	63.3 (8.0)	67.8 (6.5)	62.1 (5.6)	64.4 (7.1)	63.5 (9.1)
			Min	55	58	54	54	42
			Median	60.5	66.5	61.5	64.5	62.0
			Max	80	81	70	81	84
		6 hours	n	12	12	12	36	94
			Mean (SD)	64.9 (8.6)	69.8 (5.7)	63.0 (6.3)	65.9 (7.4)	66.0 (8.7)
			Min	53	60	54	53	46
			Median	62.5	71.5	61.5	65.5	66.0
			Max	84	78	73	84	89

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Pulse Rate [beats/min]	Day 22	Missing	n	0	0	0	0	1
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	76.0 (-)
			Min	-	-	-	-	76
			Median	-	-	-	-	76.0
			Max	-	-	-	-	76
	Day 29		n	12	12	12	36	96
			Mean (SD)	57.8 (6.2)	67.8 (11.9)	63.3 (6.9)	62.9 (9.4)	62.9 (9.5)
			Min	49	49	54	49	40
			Median	56.5	68.0	63.5	62.0	62.5
			Max	69	88	80	88	88
	Day 43		n	12	12	12	36	93
			Mean (SD)	60.8 (9.5)	72.8 (10.2)	65.2 (11.5)	66.3 (11.3)	66.1 (10.5)
			Min	44	56	46	44	44
			Median	59.0	73.0	64.0	65.5	65.0
			Max	77	87	86	87	87

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Pulse Rate [beats/min]	Day 50		n	12	11	12	35	94
			Mean (SD)	62.3 (9.2)	72.5 (10.7)	62.3 (8.2)	65.5 (10.3)	64.4 (9.9)
			Min	49	56	50	49	43
			Median	59.0	70.0	61.5	64.0	63.5
			Max	74	93	80	93	93
	Day 85		n	0	0	0	0	56
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	65.7 (10.3)
			Min	-	-	-	-	45
			Median	-	-	-	-	65.0
			Max	-	-	-	-	90
Respiratory Rate [breaths/min]	Day -30 to 0		n	12	12	12	36	96
			Mean (SD)	14.3 (1.7)	14.2 (3.3)	15.5 (1.9)	14.7 (2.4)	15.0 (3.0)
			Min	11	8	12	8	8
			Median	14.0	14.5	15.0	15.0	15.0
			Max	16	20	20	20	20

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Respiratory Rate [breaths/min]	Day 1	Predose	n	12	12	12	36	96
			Mean (SD)	13.6 (1.8)	13.3 (2.0)	12.1 (2.2)	13.0 (2.0)	14.0 (2.8)
			Min	10	9	10	9	8
			Median	14.0	13.5	11.5	13.0	14.0
			Max	16	16	16	16	20
		1 hour	n	12	12	12	36	96
			Mean (SD)	14.3 (2.0)	13.6 (3.3)	15.0 (3.2)	14.3 (2.9)	14.6 (2.7)
			Min	12	8	10	8	8
			Median	13.5	14.5	15.0	15.0	15.0
			Max	18	18	23	23	23
		3 hours	n	12	12	12	36	96
			Mean (SD)	13.8 (1.8)	13.8 (2.7)	13.0 (1.8)	13.5 (2.1)	14.5 (2.5)
			Min	11	9	10	9	8
			Median	14.0	14.5	14.0	14.0	15.0
			Max	17	17	15	17	20

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Respiratory Rate [breaths/min]	Day 1	6 hours	n	12	12	12	36	96
			Mean (SD)	14.6 (4.0)	15.6 (2.4)	17.1 (1.9)	15.8 (3.0)	15.6 (2.9)
			Min	8	10	15	8	8
			Median	14.0	16.0	16.5	16.0	16.0
			Max	20	19	21	21	21
	Day 2		n	12	12	12	36	96
			Mean (SD)	11.0 (0.9)	13.4 (2.2)	15.6 (3.3)	13.3 (3.0)	14.3 (3.0)
			Min	10	10	11	10	9
			Median	11.0	14.0	15.0	12.0	14.0
			Max	12	17	22	22	22
	Day 8		n	11	12	12	35	95
			Mean (SD)	15.7 (0.9)	15.5 (3.1)	12.9 (2.0)	14.7 (2.5)	14.9 (3.1)
			Min	15	10	11	10	8
			Median	16.0	16.0	12.0	15.0	15.0
			Max	18	21	17	21	21

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Respiratory Rate [breaths/min]	Day 22	Predose	n	12	12	12	36	94
			Mean (SD)	12.0 (2.0)	13.1 (3.2)	14.8 (2.1)	13.3 (2.7)	14.0 (2.8)
			Min	10	8	11	8	8
			Median	11.0	14.0	15.0	14.0	14.0
			Max	17	17	19	19	19
		1 hour	n	12	12	12	36	94
			Mean (SD)	13.4 (2.6)	13.4 (3.4)	14.9 (2.3)	13.9 (2.8)	14.4 (2.9)
			Min	10	8	10	8	8
			Median	14.0	14.0	15.5	14.0	15.0
			Max	18	18	18	18	19
		3 hours	n	12	12	12	36	94
			Mean (SD)	13.9 (3.1)	14.1 (3.6)	15.2 (1.4)	14.4 (2.8)	15.1 (2.8)
			Min	9	8	13	8	8
			Median	13.5	15.5	15.0	15.0	16.0
			Max	19	18	17	19	20

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Respiratory Rate [breaths/min]	Day 22	6 hours	n	12	12	12	36	94
			Mean (SD)	14.4 (2.8)	13.7 (3.4)	14.5 (1.7)	14.2 (2.7)	14.9 (3.0)
			Min	10	9	12	9	9
			Median	14.0	13.5	14.5	14.0	14.5
			Max	19	20	17	20	20
		Missing	n	0	0	0	0	1
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	17.0 (-)
			Min	-	-	-	-	17
			Median	-	-	-	-	17.0
			Max	-	-	-	-	17
	Day 29		n	12	12	12	36	96
			Mean (SD)	13.0 (2.6)	12.3 (3.5)	15.0 (1.7)	13.4 (2.9)	14.3 (3.4)
			Min	9	8	11	8	8
			Median	13.0	11.5	15.0	14.0	15.0
			Max	18	19	17	19	20

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Respiratory Rate [breaths/min]	Day 43		n	12	12	12	36	93
			Mean (SD)	14.4 (1.9)	13.6 (3.5)	15.4 (2.8)	14.5 (2.8)	14.7 (3.2)
			Min	12	8	12	8	8
			Median	14.0	13.5	15.0	15.0	15.0
			Max	18	18	22	22	22
	Day 50		n	12	11	12	35	94
			Mean (SD)	13.2 (2.4)	13.3 (3.6)	15.1 (1.9)	13.9 (2.8)	14.4 (3.3)
			Min	11	9	10	9	8
			Median	12.0	13.0	15.5	14.0	15.0
			Max	18	20	17	20	20
	Day 85		n	0	0	0	0	56
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	15.1 (3.2)
			Min	-	-	-	-	9
			Median	-	-	-	-	15.0
			Max	-	-	-	-	20

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Systolic Blood Pressure [mmHg]	Day -30 to 0		n	12	12	12	36	96
			Mean (SD)	124.8 (11.9)	122.8 (7.1)	121.7 (13.6)	123.1 (11.0)	121.4 (11.3)
			Min	103	113	102	102	100
			Median	124.5	121.5	119.0	122.5	119.5
			Max	141	136	140	141	147
	Day 1	Predose	n	12	12	12	36	96
			Mean (SD)	123.0 (12.9)	130.3 (19.2)	118.6 (11.7)	124.0 (15.3)	120.9 (13.8)
			Min	96	109	105	96	94
			Median	123.5	128.0	117.0	122.0	121.0
			Max	140	181	141	181	181
		1 hour	n	12	12	12	36	96
			Mean (SD)	114.1 (8.8)	123.3 (10.4)	114.8 (11.0)	117.4 (10.7)	116.9 (11.6)
			Min	99	106	99	99	97
			Median	116.5	125.0	112.0	120.0	116.5
			Max	127	137	136	137	147

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Systolic Blood Pressure [mmHg]	Day 1	3 hours	n	12	12	12	36	96
			Mean (SD)	113.6 (12.5)	121.3 (15.3)	112.1 (12.9)	115.6 (13.9)	116.1 (13.0)
			Min	92	95	95	92	92
			Median	112.0	121.0	109.0	114.5	115.0
			Max	138	144	133	144	167
		6 hours	n	12	12	12	36	96
			Mean (SD)	117.5 (10.0)	120.8 (16.7)	116.6 (11.3)	118.3 (12.7)	118.7 (12.4)
			Min	98	102	98	98	98
			Median	117.0	119.0	116.5	118.5	117.0
			Max	133	157	135	157	157
	Day 2		n	12	12	12	36	96
			Mean (SD)	122.9 (12.5)	121.3 (10.8)	124.8 (12.9)	123.0 (11.8)	119.1 (12.0)
			Min	107	107	103	103	95
			Median	121.5	120.5	124.5	121.5	118.0
			Max	142	141	148	148	149

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Systolic Blood Pressure [mmHg]	Day 8		n	11	12	12	35	95
			Mean (SD)	124.8 (10.3)	126.6 (11.4)	122.8 (15.3)	124.7 (12.3)	119.7 (12.4)
			Min	106	111	100	100	98
			Median	124.0	127.5	121.5	124.0	118.0
			Max	143	149	149	149	149
	Day 22	Predose	n	12	12	12	36	94
			Mean (SD)	123.0 (14.9)	121.3 (8.1)	119.7 (13.2)	121.3 (12.1)	118.4 (11.2)
			Min	104	111	99	99	95
			Median	122.0	121.0	119.0	120.5	118.0
			Max	159	138	152	159	159
		1 hour	n	12	12	12	36	94
			Mean (SD)	119.4 (10.3)	123.8 (11.7)	115.0 (12.9)	119.4 (11.9)	117.5 (11.3)
			Min	103	110	96	96	96
			Median	118.0	121.5	111.0	118.0	116.0
			Max	141	148	146	148	148

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Systolic Blood Pressure [mmHg]	Day 22	3 hours	n	12	12	12	36	94
			Mean (SD)	118.5 (10.7)	119.6 (16.1)	111.2 (13.2)	116.4 (13.6)	116.7 (12.6)
			Min	95	98	95	95	95
			Median	117.5	121.0	110.0	114.0	114.5
			Max	132	145	142	145	145
		6 hours	n	12	12	12	36	94
			Mean (SD)	120.2 (11.8)	121.5 (12.5)	116.5 (11.0)	119.4 (11.6)	118.7 (11.9)
			Min	92	106	97	92	92
			Median	121.0	116.5	113.0	117.0	117.0
			Max	135	149	137	149	149
		Missing	n	0	0	0	0	1
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	113.0 (-)
			Min	-	-	-	-	113
			Median	-	-	-	-	113.0
			Max	-	-	-	-	113

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Systolic Blood Pressure [mmHg]	Day 29		n	12	12	12	36	96
			Mean (SD)	128.2 (15.6)	123.4 (12.4)	122.2 (12.8)	124.6 (13.6)	119.1 (12.2)
			Min	94	111	110	94	94
			Median	127.0	120.0	118.5	121.0	118.5
			Max	149	146	147	149	149
	Day 43		n	12	12	12	36	93
			Mean (SD)	125.8 (11.4)	121.3 (11.2)	126.2 (16.2)	124.4 (13.0)	120.0 (11.9)
			Min	110	102	100	100	99
			Median	123.5	121.0	122.5	122.0	119.0
			Max	142	140	159	159	159
	Day 50		n	12	11	12	35	94
			Mean (SD)	128.2 (10.3)	124.3 (9.7)	117.8 (12.9)	123.4 (11.6)	118.8 (11.7)
			Min	114	111	103	103	85
			Median	126.0	124.0	114.5	121.0	119.0
			Max	149	137	142	149	150

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Systolic Blood Pressure [mmHg]	Day 85		n	0	0	0	0	56
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	119.7 (12.4)
			Min	-	-	-	-	94
			Median	-	-	-	-	117.5
			Max	-	-	-	-	155
Temperature [°C]	Day -30 to 0		n	12	12	12	36	96
			Mean (SD)	36.24 (0.29)	36.44 (0.23)	36.08 (0.19)	36.26 (0.28)	36.29 (0.28)
			Min	36.0	36.0	35.7	35.7	35.6
			Median	36.20	36.40	36.10	36.20	36.30
			Max	36.9	36.7	36.5	36.9	36.9
	Day 1	Predose	n	12	12	12	36	96
			Mean (SD)	36.34 (0.16)	36.21 (0.32)	36.29 (0.17)	36.28 (0.23)	36.29 (0.31)
			Min	36.1	35.7	36.1	35.7	35.5
			Median	36.30	36.15	36.30	36.30	36.30
			Max	36.6	37.0	36.5	37.0	37.2

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Temperature [°C]	Day 1	1 hour	n	12	12	12	36	96
			Mean (SD)	36.18 (0.24)	35.98 (0.29)	36.21 (0.16)	36.12 (0.25)	36.18 (0.31)
			Min	35.6	35.5	36.0	35.5	35.5
			Median	36.10	36.00	36.20	36.10	36.10
			Max	36.5	36.4	36.5	36.5	36.9
		3 hours	n	12	12	12	36	96
			Mean (SD)	36.21 (0.27)	36.01 (0.26)	36.33 (0.30)	36.18 (0.30)	36.27 (0.31)
			Min	36.0	35.5	35.9	35.5	35.3
			Median	36.10	36.10	36.30	36.10	36.30
			Max	36.9	36.3	36.9	36.9	36.9
		6 hours	n	12	12	12	36	96
			Mean (SD)	36.28 (0.30)	36.41 (0.38)	36.30 (0.33)	36.33 (0.33)	36.42 (0.34)
			Min	35.9	35.6	35.9	35.6	35.6
			Median	36.30	36.50	36.30	36.30	36.45
			Max	36.8	36.9	36.8	36.9	37.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Temperature [°C]	Day 2		n	12	12	12	36	96
			Mean (SD)	36.29 (0.16)	36.31 (0.37)	36.44 (0.55)	36.35 (0.39)	36.34 (0.34)
			Min	36.1	35.7	35.5	35.5	35.5
			Median	36.25	36.30	36.30	36.30	36.30
			Max	36.6	36.9	37.4	37.4	37.4
	Day 8		n	11	12	12	35	95
			Mean (SD)	36.06 (0.24)	36.01 (0.27)	36.26 (0.31)	36.11 (0.29)	36.18 (0.33)
			Min	35.7	35.7	35.5	35.5	35.5
			Median	36.00	36.00	36.25	36.20	36.20
			Max	36.4	36.4	36.8	36.8	37.5
	Day 22	Predose	n	11	12	12	35	93
			Mean (SD)	36.15 (0.30)	36.43 (0.48)	36.28 (0.35)	36.29 (0.39)	36.32 (0.36)
			Min	35.5	35.6	35.8	35.5	35.5
			Median	36.20	36.60	36.35	36.30	36.30
			Max	36.5	36.9	36.8	36.9	37.1

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Temperature [°C]	Day 22	1 hour	n	12	12	12	36	94
			Mean (SD)	36.09 (0.26)	36.23 (0.26)	36.18 (0.40)	36.17 (0.31)	36.13 (0.30)
			Min	35.7	35.8	35.6	35.6	35.6
			Median	36.10	36.30	36.05	36.10	36.10
			Max	36.6	36.6	36.9	36.9	36.9
		3 hours	n	12	12	12	36	94
			Mean (SD)	36.14 (0.13)	36.39 (0.28)	36.13 (0.35)	36.22 (0.29)	36.29 (0.32)
			Min	35.9	36.0	35.6	35.6	35.6
			Median	36.10	36.30	36.05	36.20	36.30
			Max	36.3	37.0	36.9	37.0	37.0
		6 hours	n	12	12	11	35	93
			Mean (SD)	36.14 (0.27)	36.45 (0.40)	35.95 (0.25)	36.19 (0.37)	36.39 (0.38)
			Min	35.7	35.7	35.5	35.5	35.5
			Median	36.20	36.55	35.90	36.20	36.50
			Max	36.5	36.9	36.4	36.9	37.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Temperature [°C]	Day 22	Missing	n	0	0	0	0	1
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	36.10 (-)
			Min	-	-	-	-	36.1
			Median	-	-	-	-	36.10
			Max	-	-	-	-	36.1
	Day 29		n	12	12	12	36	96
			Mean (SD)	36.06 (0.38)	36.18 (0.32)	36.25 (0.37)	36.16 (0.36)	36.22 (0.36)
			Min	35.5	35.7	35.8	35.5	35.5
			Median	36.05	36.20	36.25	36.20	36.20
			Max	36.6	36.7	36.9	36.9	37.0
	Day 43		n	12	12	12	36	93
			Mean (SD)	35.97 (0.28)	36.29 (0.35)	36.32 (0.30)	36.19 (0.34)	36.27 (0.36)
			Min	35.6	35.5	35.9	35.5	35.5
			Median	35.95	36.40	36.30	36.15	36.30
			Max	36.6	36.6	36.9	36.9	37.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.1-3: Vital signs: Descriptive statistics - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12)	20 µg (N=12)	30 µg (N=12)	Total (N=36)	Total (N=96)
Temperature [°C]	Day 50		n	12	11	12	35	94
			Mean (SD)	36.23 (0.32)	36.07 (0.39)	36.10 (0.30)	36.13 (0.33)	36.22 (0.32)
			Min	35.7	35.5	35.6	35.5	35.5
			Median	36.25	36.10	36.10	36.10	36.30
			Max	36.8	36.6	36.6	36.8	37.1
	Day 85		n	0	0	0	0	55
			Mean (SD)	- (-)	- (-)	- (-)	- (-)	36.31 (0.32)
			Min	-	-	-	-	35.6
			Median	-	-	-	-	36.40
			Max	-	-	-	-	37.0

SD is only calculated if values of at least 3 subjects are available.
N = number of subjects in the analysis set; n = number of subjects with data available; SD = standard deviation; - = not estimable.

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Table 14.3.2-3.3-3: Vital signs: Abnormal and clinically significant values per visit - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Diastolic Blood Pressure [mmHg]	Day -30 to 0		Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	2 (17)	3 (5)
			Normal	11 (92)	12 (100)	12 (100)	12 (100)	10 (83)	57 (95)
	Day 1	Predose	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
		1 hour	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	2 (3)
			Normal	11 (92)	12 (100)	12 (100)	12 (100)	11 (92)	58 (97)
		3 hours	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
			Normal	12 (100)	12 (100)	11 (92)	12 (100)	12 (100)	59 (98)
		6 hours	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
			Normal	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	59 (98)
	Day 2		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	1 (8)	2 (3)
			Normal	12 (100)	12 (100)	12 (100)	11 (92)	11 (92)	58 (97)
	Day 8		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
			Normal	12 (100)	12 (100)	12 (100)	11 (92)	11 (92)	58 (97)
			Normal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)	1 (2)
	Day 22	Predose	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
			Normal	11 (92)	12 (100)	11 (92)	12 (100)	11 (92)	57 (95)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-3.3-3: Vital signs: Abnormal and clinically significant values per visit - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Diastolic Blood Pressure [mmHg]	Day 22	1 hour	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
			Normal	11 (92)	12 (100)	11 (92)	12 (100)	11 (92)	57 (95)
		3 hours	Normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
		6 hours	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
			Normal	11 (92)	12 (100)	10 (83)	12 (100)	11 (92)	56 (93)
			Normal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	0 (0)	1 (2)
		Missing	Normal	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
	Day 29		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
			Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 43		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
			Normal	11 (92)	12 (100)	11 (92)	12 (100)	11 (92)	57 (95)
	Day 50		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
			Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	59 (98)
	Day 85		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (17)	2 (3)
			Normal	11 (92)	10 (83)	11 (92)	12 (100)	10 (83)	54 (90)
Pulse Rate [beats/min]	Day -30 to 0		Abnormal (not CS)	1 (8)	1 (8)	0 (0)	1 (8)	0 (0)	3 (5)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-3.3-3: Vital signs: Abnormal and clinically significant values per visit - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Pulse Rate [beats/min]	Day -30 to 0		Normal	11 (92)	11 (92)	12 (100)	11 (92)	12 (100)	57 (95)
	Day 1	Predose	Abnormal (not CS)	2 (17)	1 (8)	0 (0)	0 (0)	0 (0)	3 (5)
			Normal	10 (83)	11 (92)	12 (100)	12 (100)	12 (100)	57 (95)
		1 hour	Abnormal (not CS)	8 (67)	1 (8)	2 (17)	2 (17)	1 (8)	14 (23)
			Normal	4 (33)	11 (92)	10 (83)	10 (83)	11 (92)	46 (77)
		3 hours	Abnormal (not CS)	3 (25)	0 (0)	1 (8)	0 (0)	0 (0)	4 (7)
			Normal	9 (75)	12 (100)	11 (92)	12 (100)	12 (100)	56 (93)
		6 hours	Abnormal (not CS)	1 (8)	2 (17)	0 (0)	1 (8)	0 (0)	4 (7)
			Normal	11 (92)	10 (83)	12 (100)	11 (92)	12 (100)	56 (93)
	Day 2		Abnormal (not CS)	2 (17)	1 (8)	0 (0)	1 (8)	0 (0)	4 (7)
			Normal	10 (83)	11 (92)	12 (100)	11 (92)	12 (100)	56 (93)
	Day 8		Abnormal (not CS)	4 (33)	0 (0)	0 (0)	1 (8)	0 (0)	5 (8)
			Normal	8 (67)	12 (100)	12 (100)	11 (92)	12 (100)	55 (92)
	Day 22	Predose	Abnormal (not CS)	2 (17)	1 (8)	1 (8)	1 (8)	0 (0)	5 (8)
			Normal	9 (75)	11 (92)	10 (83)	11 (92)	12 (100)	53 (88)
		1 hour	Abnormal (not CS)	5 (42)	2 (17)	2 (17)	1 (8)	1 (8)	11 (18)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-3.3-3: Vital signs: Abnormal and clinically significant values per visit - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Pulse Rate [beats/min]	Day 22	1 hour	Normal	6 (50)	10 (83)	9 (75)	11 (92)	11 (92)	47 (78)
		3 hours	Abnormal (not CS)	3 (25)	2 (17)	0 (0)	0 (0)	1 (8)	6 (10)
			Normal	8 (67)	10 (83)	11 (92)	12 (100)	11 (92)	52 (87)
		6 hours	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
			Normal	10 (83)	12 (100)	11 (92)	12 (100)	12 (100)	57 (95)
		Missing	Normal	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
	Day 29		Abnormal (not CS)	4 (33)	1 (8)	0 (0)	1 (8)	0 (0)	6 (10)
			Normal	8 (67)	11 (92)	12 (100)	11 (92)	12 (100)	54 (90)
	Day 43		Abnormal (not CS)	2 (17)	0 (0)	1 (8)	1 (8)	0 (0)	4 (7)
			Normal	9 (75)	12 (100)	10 (83)	11 (92)	11 (92)	53 (88)
	Day 50		Abnormal (not CS)	3 (25)	0 (0)	1 (8)	1 (8)	0 (0)	5 (8)
			Normal	8 (67)	12 (100)	11 (92)	11 (92)	12 (100)	54 (90)
	Day 85		Abnormal (not CS)	2 (17)	0 (0)	0 (0)	1 (8)	0 (0)	3 (5)
			Normal	9 (75)	10 (83)	11 (92)	11 (92)	12 (100)	53 (88)
Respiratory Rate [breaths/min]	Day -30 to 0		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 1	Predose	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_VS_3_3.sas (Page 4 of 18)

Table 14.3.2-3.3-3: Vital signs: Abnormal and clinically significant values per visit - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Respiratory Rate [breaths/min]	Day 1	1 hour	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
			Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
		3 hours	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
		6 hours	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
			Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 2		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
			Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 8		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
			Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 22	Predose	Normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
		1 hour	Normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
		3 hours	Normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
		6 hours	Normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
		Missing	Normal	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
	Day 29		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 43		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-3.3-3: Vital signs: Abnormal and clinically significant values per visit - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Respiratory Rate [breaths/min]	Day 43		Normal	11 (92)	12 (100)	11 (92)	12 (100)	11 (92)	57 (95)
	Day 50		Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	59 (98)
	Day 85		Normal	11 (92)	10 (83)	11 (92)	12 (100)	12 (100)	56 (93)
Systolic Blood Pressure [mmHg]	Day -30 to 0		Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (8)	2 (17)	4 (7)
			Normal	12 (100)	11 (92)	12 (100)	11 (92)	10 (83)	56 (93)
	Day 1	Predose	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	1 (8)	2 (17)	3 (5)
			Normal	12 (100)	12 (100)	12 (100)	11 (92)	10 (83)	57 (95)
		1 hour	Abnormal (not CS)	1 (8)	1 (8)	0 (0)	0 (0)	2 (17)	4 (7)
			Normal	11 (92)	11 (92)	12 (100)	12 (100)	10 (83)	56 (93)
		3 hours	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
			Normal	12 (100)	12 (100)	11 (92)	12 (100)	11 (92)	58 (97)
		6 hours	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	2 (17)	3 (5)
			Normal	12 (100)	12 (100)	11 (92)	12 (100)	10 (83)	57 (95)
	Day 2		Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (8)	0 (0)	2 (3)
			Normal	12 (100)	12 (100)	11 (92)	11 (92)	12 (100)	58 (97)
	Day 8		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-3.3-3: Vital signs: Abnormal and clinically significant values per visit - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Systolic Blood Pressure [mmHg]	Day 8		Normal	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	59 (98)
	Day 22	Predose	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
			Normal	11 (92)	12 (100)	11 (92)	12 (100)	11 (92)	57 (95)
		1 hour	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
			Normal	11 (92)	12 (100)	11 (92)	12 (100)	11 (92)	57 (95)
		3 hours	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	2 (3)
			Normal	10 (83)	12 (100)	10 (83)	12 (100)	12 (100)	56 (93)
		6 hours	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	0 (0)	1 (8)	2 (3)
			Normal	11 (92)	12 (100)	10 (83)	12 (100)	11 (92)	56 (93)
		Missing	Normal	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
	Day 29		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
			Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 43		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
			Normal	11 (92)	12 (100)	11 (92)	12 (100)	10 (83)	56 (93)
	Day 50		Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (8)	1 (8)	3 (5)
			Normal	11 (92)	12 (100)	11 (92)	11 (92)	11 (92)	56 (93)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-3.3-3: Vital signs: Abnormal and clinically significant values per visit - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Systolic Blood Pressure [mmHg]	Day 85		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
			Normal	11 (92)	10 (83)	11 (92)	12 (100)	11 (92)	55 (92)
Temperature [°C]	Day -30 to 0		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 1	Predose	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
		1 hour	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
		3 hours	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (8)	1 (2)
			Normal	12 (100)	12 (100)	12 (100)	12 (100)	11 (92)	59 (98)
		6 hours	Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 2		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 8		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)
	Day 22	Predose	Normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
		1 hour	Normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
		3 hours	Normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
		6 hours	Normal	11 (92)	12 (100)	11 (92)	12 (100)	12 (100)	58 (97)
		Missing	Normal	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
	Day 29		Normal	12 (100)	12 (100)	12 (100)	12 (100)	12 (100)	60 (100)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-3.3-3: Vital signs: Abnormal and clinically significant values per visit - BNT162b2

Safety set

				Younger dose ranging cohorts					
Parameter [Unit]	Visit	Timepoint		1 µg (N=12) n (%)	3 µg (N=12) n (%)	10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=60) n (%)
Temperature [°C]	Day 43		Normal	11 (92)	12 (100)	11 (92)	12 (100)	11 (92)	57 (95)
	Day 50		Normal	11 (92)	12 (100)	12 (100)	12 (100)	12 (100)	59 (98)
	Day 85		Normal	11 (92)	9 (75)	11 (92)	12 (100)	12 (100)	55 (92)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-3.3-3: Vital signs: Abnormal and clinically significant values per visit - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Diastolic Blood Pressure [mmHg]	Day -30 to 0		Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (6)	5 (5)
			Normal	11 (92)	11 (92)	12 (100)	34 (94)	91 (95)
	Day 1	Predose	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
		1 hour	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
			Normal	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
		3 hours	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	12 (100)	12 (100)	12 (100)	36 (100)	95 (99)
		6 hours	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	12 (100)	12 (100)	12 (100)	36 (100)	95 (99)
	Day 2		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
			Normal	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
	Day 8		Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
			Normal	10 (83)	12 (100)	12 (100)	34 (94)	92 (96)
			Normal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 22	Predose	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	12 (100)	12 (100)	12 (100)	36 (100)	93 (97)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-3.3-3: Vital signs: Abnormal and clinically significant values per visit - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Diastolic Blood Pressure [mmHg]	Day 22	1 hour	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
			Normal	11 (92)	12 (100)	12 (100)	35 (97)	92 (96)
		3 hours	Normal	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
		6 hours	Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	2 (2)
			Normal	11 (92)	12 (100)	12 (100)	35 (97)	91 (95)
			Normal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
		Missing	Normal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 29		Abnormal (not CS)	3 (25)	0 (0)	0 (0)	3 (8)	3 (3)
			Normal	9 (75)	12 (100)	12 (100)	33 (92)	93 (97)
	Day 43		Abnormal (not CS)	3 (25)	0 (0)	0 (0)	3 (8)	3 (3)
			Normal	9 (75)	12 (100)	12 (100)	33 (92)	90 (94)
	Day 50		Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	1 (1)
			Normal	11 (92)	11 (92)	12 (100)	34 (94)	93 (97)
	Day 85		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	2 (2)
			Normal	0 (0)	0 (0)	0 (0)	0 (0)	54 (56)
Pulse Rate [beats/min]	Day -30 to 0		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

Program: Tfsaf_VS_3_3.sas (Page 11 of 18)

Table 14.3.2-3.3-3: Vital signs: Abnormal and clinically significant values per visit - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Pulse Rate [beats/min]	Day -30 to 0		Normal	12 (100)	12 (100)	12 (100)	36 (100)	93 (97)
	Day 1	Predose	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
			Normal	12 (100)	12 (100)	12 (100)	36 (100)	93 (97)
		1 hour	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	14 (15)
			Normal	12 (100)	12 (100)	12 (100)	36 (100)	82 (85)
		3 hours	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	5 (5)
			Normal	12 (100)	12 (100)	11 (92)	35 (97)	91 (95)
		6 hours	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
			Normal	12 (100)	12 (100)	12 (100)	36 (100)	92 (96)
	Day 2		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
			Normal	12 (100)	12 (100)	12 (100)	36 (100)	92 (96)
	Day 8		Abnormal (not CS)	2 (17)	0 (0)	0 (0)	2 (6)	7 (7)
			Normal	9 (75)	12 (100)	12 (100)	33 (92)	88 (92)
	Day 22	Predose	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	5 (5)
			Normal	12 (100)	12 (100)	12 (100)	36 (100)	89 (93)
		1 hour	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	11 (11)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-3.3-3: Vital signs: Abnormal and clinically significant values per visit - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Pulse Rate [beats/min]	Day 22	1 hour	Normal	12 (100)	12 (100)	12 (100)	36 (100)	83 (86)
		3 hours	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	6 (6)
			Normal	12 (100)	12 (100)	12 (100)	36 (100)	88 (92)
		6 hours	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	12 (100)	12 (100)	12 (100)	36 (100)	93 (97)
		Missing	Normal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 29		Abnormal (not CS)	1 (8)	1 (8)	0 (0)	2 (6)	8 (8)
			Normal	11 (92)	11 (92)	12 (100)	34 (94)	88 (92)
	Day 43		Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	6 (6)
			Normal	11 (92)	12 (100)	11 (92)	34 (94)	87 (91)
	Day 50		Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	6 (6)
			Normal	11 (92)	11 (92)	12 (100)	34 (94)	88 (92)
	Day 85		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)
			Normal	0 (0)	0 (0)	0 (0)	0 (0)	53 (55)
Respiratory Rate [breaths/min]	Day -30 to 0		Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 1	Predose	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-3.3-3: Vital signs: Abnormal and clinically significant values per visit - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Respiratory Rate [breaths/min]	Day 1	1 hour	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
			Normal	12 (100)	12 (100)	11 (92)	35 (97)	95 (99)
		3 hours	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
		6 hours	Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)
			Normal	12 (100)	12 (100)	11 (92)	35 (97)	95 (99)
	Day 2		Abnormal (not CS)	0 (0)	0 (0)	2 (17)	2 (6)	2 (2)
			Normal	12 (100)	12 (100)	10 (83)	34 (94)	94 (98)
	Day 8		Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	1 (1)
			Normal	11 (92)	11 (92)	12 (100)	34 (94)	94 (98)
	Day 22	Predose	Normal	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
		1 hour	Normal	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
		3 hours	Normal	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
		6 hours	Normal	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
		Missing	Normal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 29		Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 43		Abnormal (not CS)	0 (0)	0 (0)	1 (8)	1 (3)	1 (1)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-3.3-3: Vital signs: Abnormal and clinically significant values per visit - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Respiratory Rate [breaths/min]	Day 43		Normal	12 (100)	12 (100)	11 (92)	35 (97)	92 (96)
	Day 50		Normal	12 (100)	11 (92)	12 (100)	35 (97)	94 (98)
	Day 85		Normal	0 (0)	0 (0)	0 (0)	0 (0)	56 (58)
Systolic Blood Pressure [mmHg]	Day -30 to 0		Abnormal (not CS)	1 (8)	0 (0)	0 (0)	1 (3)	5 (5)
			Normal	11 (92)	12 (100)	12 (100)	35 (97)	91 (95)
	Day 1	Predose	Abnormal (not CS)	0 (0)	2 (17)	1 (8)	3 (8)	6 (6)
			Normal	12 (100)	10 (83)	11 (92)	33 (92)	90 (94)
		1 hour	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
			Normal	12 (100)	12 (100)	12 (100)	36 (100)	92 (96)
		3 hours	Abnormal (not CS)	0 (0)	2 (17)	0 (0)	2 (6)	4 (4)
			Normal	12 (100)	10 (83)	12 (100)	34 (94)	92 (96)
		6 hours	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	4 (4)
			Normal	12 (100)	11 (92)	12 (100)	35 (97)	92 (96)
	Day 2		Abnormal (not CS)	1 (8)	1 (8)	2 (17)	4 (11)	6 (6)
			Normal	11 (92)	11 (92)	10 (83)	32 (89)	90 (94)
	Day 8		Abnormal (not CS)	1 (8)	1 (8)	2 (17)	4 (11)	5 (5)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-3.3-3: Vital signs: Abnormal and clinically significant values per visit - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Systolic Blood Pressure [mmHg]	Day 8		Normal	10 (83)	11 (92)	10 (83)	31 (86)	90 (94)
	Day 22	Predose	Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	3 (3)
			Normal	11 (92)	12 (100)	11 (92)	34 (94)	91 (95)
		1 hour	Abnormal (not CS)	1 (8)	1 (8)	1 (8)	3 (8)	4 (4)
			Normal	11 (92)	11 (92)	11 (92)	33 (92)	90 (94)
		3 hours	Abnormal (not CS)	0 (0)	2 (17)	1 (8)	3 (8)	5 (5)
			Normal	12 (100)	10 (83)	11 (92)	33 (92)	89 (93)
		6 hours	Abnormal (not CS)	0 (0)	1 (8)	0 (0)	1 (3)	3 (3)
			Normal	12 (100)	11 (92)	12 (100)	35 (97)	91 (95)
		Missing	Normal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 29		Abnormal (not CS)	3 (25)	3 (25)	2 (17)	8 (22)	8 (8)
			Normal	9 (75)	9 (75)	10 (83)	28 (78)	88 (92)
	Day 43		Abnormal (not CS)	1 (8)	0 (0)	2 (17)	3 (8)	4 (4)
			Normal	11 (92)	12 (100)	10 (83)	33 (92)	89 (93)
	Day 50		Abnormal (not CS)	1 (8)	0 (0)	1 (8)	2 (6)	5 (5)
			Normal	11 (92)	11 (92)	11 (92)	33 (92)	89 (93)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-3.3-3: Vital signs: Abnormal and clinically significant values per visit - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Systolic Blood Pressure [mmHg]	Day 85		Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	0 (0)	0 (0)	0 (0)	0 (0)	55 (57)
Temperature [°C]	Day -30 to 0		Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 1	Predose	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
		1 hour	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
		3 hours	Abnormal (not CS)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
			Normal	12 (100)	12 (100)	12 (100)	36 (100)	95 (99)
		6 hours	Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 2		Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)
	Day 8		Normal	11 (92)	12 (100)	12 (100)	35 (97)	95 (99)
	Day 22	Predose	Normal	11 (92)	12 (100)	12 (100)	35 (97)	93 (97)
		1 hour	Normal	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
		3 hours	Normal	12 (100)	12 (100)	12 (100)	36 (100)	94 (98)
		6 hours	Normal	12 (100)	12 (100)	11 (92)	35 (97)	93 (97)
		Missing	Normal	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
	Day 29		Normal	12 (100)	12 (100)	12 (100)	36 (100)	96 (100)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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Table 14.3.2-3.3-3: Vital signs: Abnormal and clinically significant values per visit - BNT162b2

Safety set

				Older dose ranging cohorts				
Parameter [Unit]	Visit	Timepoint		10 µg (N=12) n (%)	20 µg (N=12) n (%)	30 µg (N=12) n (%)	Total (N=36) n (%)	Total (N=96) n (%)
Temperature [°C]	Day 43		Normal	12 (100)	12 (100)	12 (100)	36 (100)	93 (97)
	Day 50		Normal	12 (100)	11 (92)	12 (100)	35 (97)	94 (98)
	Day 85		Normal	0 (0)	0 (0)	0 (0)	0 (0)	55 (57)

The denominator for the percentage calculation is N.
CS = clinically significant; N = number of subjects in the analysis set; n = number of subjects with the specified characteristic.

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