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.

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.