

**Listing 16.2.1-2-1: Listing of protocol deviations - BNT162b1**

Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
1 µg Younger	10015	Phone call was not performed	Acc. to CTP 3.0 section 'trial design' not necessary	Visit Schedule Compliance	Phone Call at 48h, Phone Call	01MAY2020
		The measurement was not performed in the scheduled time Frame	logistic reason	Visit Schedule Compliance	Visit 1, 12-lead ECG	29APR2020
		The measurement was not performed in the scheduled time frame	logistic reason	Visit Schedule Compliance	Visit 1, Body Temperature, predose	29APR2020
		The measurement was not performed in the scheduled time frame	logistic reason	Visit Schedule Compliance	Visit 1, Vital Signs, predose	29APR2020
		Urine pregnancy testing performed	Done by mistake	Laboratory Data, ECG Data, Pregnancy Data	Visit 1, Urine Pregnancy Test	29APR2020
	10018	FSH was not determined.	Done by mistake.	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	23APR2020
		Measurements (Vital Signs, ECG) not prior to Allocation	done by mistake	Visit Schedule Compliance	Visit 1, predose	29APR2020
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Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

**Listing 16.2.1-2-1: Listing of protocol deviations - BNT162b1**

Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
1 µg Younger	10018	Phone call was not performed	Acc. to CTP 3.0 section 'trial design' not necessary	Visit Schedule Compliance	Phone Call at 48h, Phone Call	01MAY2020
		The measurement was not performed in the scheduled time frame.	logistic reason	Visit Schedule Compliance	Visit 1, Body Temperature, predose	29APR2020
	10023	Phone call was not performed	Acc. to CTP 3.0 section 'trial design' not necessary	Visit Schedule Compliance	Phone Call at 48h, Phone Call	07MAY2020
	10025	Measurement not prior to Allocation	done by mistake	Visit Schedule Compliance	Visit 1, Physical Examination	05MAY2020
		Phone call was not performed	Acc. to CTP 3.0 section 'trial design' not necessary	Visit Schedule Compliance	Phone Call at 48h, Phone Call	07MAY2020
	10033	Phone call was not performed	Acc. to CTP 3.0 section 'trial design' not necessary	Visit Schedule Compliance	Phone Call at 48h, Phone Call	07MAY2020
		The measurements were not performed in the scheduled timeframe.	Due to logistical reason measurements at timepoints 1h, 3h and 6h after vaccination were performed out of the given timeframe (+/- 15 min.)	Visit Schedule Compliance	Visit 4, Body Temperature, 1h, 3h, 6h after vaccination	26MAY2020
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**Listing 16.2.1-2-1: Listing of protocol deviations - BNT162b1**

Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
1 µg Younger	10033	The measurements were not performed in the scheduled timeframe.	Due to logistical reason measurements at timepoints 1h, 3h and 6h after vaccination were performed out of the given timeframe (+/- 15 min.)	Visit Schedule Compliance	Visit 4, Vital Signs, 1h, 3h, 6h after vaccination	26MAY2020
		The measurements were not performed in the scheduled timeframe.	Due to logistical reason measurements at timepoints 1h, 3h and 6h after vaccination were performed out of the given timeframe (+/- 15 min.)	Visit Schedule Compliance	Visit 4, Local Tolerability at Injection Site, 1h, 3h, 6h after vaccination	26MAY2020
	10036	Diary entries for Day 04.06.2020 for Local and Systemic Reactions are not available.	Missing entries.	Other	Visit 5	04JUN2020
	10040	Diary entries for Day 04.06.2020 for Local and Systemic Reactions are not available.	Missing entries.	Other	Visit 5	04JUN2020
	10041	Diary Entries for Day 04.06.2020 for Local and Systemic Reactions are not available	Missing Entries	Other	Visit 5	04JUN2020
		FSH Level was not determined.	Done by mistake.	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	28APR2020
	10042	Diary entries for Day 04.06.2020 for Local and Systemic Reactions are not available.	Missing entries.	Other	Visit 5	04JUN2020
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Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
1 µg Younger	10045	Diary entries for Day 02.06.2020 for Local and Systemic Reactions are not available.	Missing entries	Other	Visit 5	02JUN2020
		FSH Level was not determined.	Done by mistake	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	28APR2020
		Phone call was not performed	Acc. to CTP 3.0 section 'trial design' not necessary	Visit Schedule Compliance	Phone Call at 48h, Phone Call	07MAY2020
		The measurements were not performed in the scheduled timeframe	Due to logistical reason measurements at timepoints 1h, 3h and 6h after vaccination were performed out of the given timeframe (+/- 15 min.)	Visit Schedule Compliance	Visit 4, Body Temperature, 1h, 3h, 6h after vaccination	26MAY2020
		The measurements were not performed in the scheduled timeframe	Due to logistical reason measurements at timepoints 1h, 3h and 6h after vaccination were performed out of the given timeframe (+/- 15 min.)	Visit Schedule Compliance	Visit 4, Vital Signs, 1h, 3h, 6h after vaccination	26MAY2020
		The measurements were not performed in the scheduled timeframe	Due to logistical reason measurements at timepoints 1h, 3h and 6h after vaccination were performed out of the given timeframe (+/- 15 min.)	Visit Schedule Compliance	Visit 4, Local Tolerability at Injection Site, 1h, 3h, 6h after vaccination	26MAY2020
	10048	Diary entries for Day 04.06.2020 for Local and Systemic Reactions are not available.	Missing entries.	Other	Visit 5	04JUN2020
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**Listing 16.2.1-2-1: Listing of protocol deviations - BNT162b1**

Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
1 µg Younger	10048	Visit 7 not performed	Due to private reason of the subject Visit 7 was not performed	Visit Schedule Compliance	Visit 7 (a1, b1, b2, c2P/B) (EoT)	25JUN2020
	10052	Diary entries for Day 03.06.2020 for Local and Systemic Reactions are not available.	Missing entries.	Other	Visit 5	03JUN2020
		Diary entries for Day 04.06.2020 for Local and Systemic Reactions are not available.	Missing entries.	Other	Visit 5	04JUN2020
3 µg Younger	10170	Vital Signs and Body Temperature measurements performed, but values not documented	values not entered by mistake	Other	Visit 3	07AUG2020
	10194	FSH Level was determined	done by mistake	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	13JUL2020
		Phone call was not performed	not performed by mistake	Visit Schedule Compliance	Phone Call at 48h, Phone Call	24JUL2020
		diary entries for local reactions are entered for only 5 consecutive days after V4 (day 23-27)	done by mistake, cause Visit 5 was scheduled and performed for day 28, so no entries were at site by subject itself	Treatment Compliance	Visit 5, Diary - Local Reactions	18AUG2020
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Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
3 µg Younger	10194	diary entries for local reactions are entered for only 5 consecutive days after V4 (day 23-27)	done by mistake, cause Visit 5 was scheduled and performed for day 28, so no entries were at site by subject itself	Treatment Compliance	Visit 5, Diary - Systemic Reactions	18AUG2020
	10198	FSH Level was determined	done by mistake	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	15JUL2020
		Phone call was not performed	not performed by mistake	Visit Schedule Compliance	Phone Call at 48h, Phone Call	24JUL2020
	10200	Phone call was not performed	not performed by mistake	Visit Schedule Compliance	Phone Call at 48h, Phone Call	24JUL2020
		diary entries for local and systemic reactions are entered for only 5 consecutive days after V4 (day 23-27)	done by mistake, cause Visit 5 was scheduled and performed for day 28, so no entries were at site by subject itself	Treatment Compliance	Visit 5, Diary - Local Reactions	18AUG2020
		diary entries for local and systemic reactions are entered for only 5 consecutive days after V4 (day 23-27)	done by mistake, cause Visit 5 was scheduled and performed for day 28, so no entries were at site by subject itself	Treatment Compliance	Visit 5, Diary - Systemic Reactions	18AUG2020
	10204	Phone call was not performed	not performed by mistake	Visit Schedule Compliance	Phone Call at 48h, Phone Call	24JUL2020
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Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
3 µg Younger	10204	diary entries for local and systemic reactions are entered for only 5 consecutive days after V4 (day 23-27)	done by mistake, cause Visit 5 was scheduled and performed for day 28, so no entries were at site by subject itself	Treatment Compliance	Visit 5, Diary - Local Reactions	18AUG2020
		diary entries for local and systemic reactions are entered for only 5 consecutive days after V4 (day 23-27)	done by mistake, cause Visit 5 was scheduled and performed for day 28, so no entries were at site by subject itself	Treatment Compliance	Visit 5, Diary - Systemic Reactions	18AUG2020
	10209	Phone call was not performed	not performed by mistake	Visit Schedule Compliance	Phone Call at 48h, Phone Call	24JUL2020
		diary entries for local and systemic reactions are entered for only 5 consecutive days after V4 (day 23-27)	done by mistake, cause Visit 5 was scheduled and performed for day 28, so no entries were at site by subject itself	Treatment Compliance	Visit 5, Diary - Local Reactions	18AUG2020
		diary entries for local and systemic reactions are entered for only 5 consecutive days after V4 (day 23-27)	done by mistake, cause Visit 5 was scheduled and performed for day 28, so no entries were at site by subject itself	Treatment Compliance	Visit 5, Diary - Systemic Reactions	18AUG2020
		urine pregnancy testing performed	done by mistake	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Urine Pregnancy Test	17JUL2020
	10212	Phone call was not performed	not performed by mistake	Visit Schedule Compliance	Phone Call at 48h, Phone Call	24JUL2020
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Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
3 µg Younger	10212	diary entries for local and systemic reactions are entered for only 5 consecutive days after V4 (day 23-27)	done by mistake, cause Visit 5 was scheduled and performed for day 28, so no entries were at site by subject itself	Treatment Compliance	Visit 5, Diary - Local Reactions	18AUG2020
		diary entries for local and systemic reactions are entered for only 5 consecutive days after V4 (day 23-27)	done by mistake, cause Visit 5 was scheduled and performed for day 28, so no entries were at site by subject itself	Treatment Compliance	Visit 5, Diary - Systemic Reactions	18AUG2020
	10221	Body temperature time is not correct entered, time is unknown	Body temperature measured right after vitals signs, time entered (12:30 h) by mistake. Correct time is unknown	Visit Schedule Compliance	Visit 4, Body Temperature, 3 h a.v.	21AUG2020
10 µg Younger	10001	FSH Level was not determined.	Done by mistake.	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	22APR2020
	10003	FSH Level was not determined.	Done by mistake.	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	22APR2020
	10005	FSH Level was not determined.	Done by mistake.	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	22APR2020
	10007	Visit 5 was postponed	Due to urgent private reason visit was postponed in agreement with investigator	Visit Schedule Compliance	Visit 5	25MAY2020
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Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
10 µg Younger	10008	FSH Level was not determined.	Done by mistake.	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	22APR2020
		The measurement was not performed in the scheduled time frame.	logistic reason	Visit Schedule Compliance	Visit 1, Body Temperature, predose	28APR2020
		The measurement was not performed in the scheduled time frame.	logistic reason	Visit Schedule Compliance	Visit 1, Vital Signs, predose	28APR2020
		The measurement was not performed in the scheduled time frame.	logistic reason	Visit Schedule Compliance	Visit 1, 12-lead ECG	28APR2020
	10017	FSH Level was not determined.	Done by mistake.	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	23APR2020
		Measurements (Vital Signs, ECG) not prior to Allocation	done by mistake	Visit Schedule Compliance	Visit 1, predose	28APR2020
		The measurement was not performed in the scheduled time frame.	logistic reason	Visit Schedule Compliance	Visit 1, Body Temperature, predose	28APR2020
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Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
10 µg Younger	10019	Measurements (Vital Signs, ECG) not prior to Allocation	done by mistake	Visit Schedule Compliance	Visit 1, predose	28APR2020
		The measurement was not performed in the scheduled time frame.	logistic reason	Visit Schedule Compliance	Visit 1, Body Temperature, predose	28APR2020
20 µg Younger	10151	Measurements (Body temp./Vital signs/ECG) not prior to Allocation	done by mistake	Visit Schedule Compliance	Visit 1, predose	16JUL2020
		Phone call was not performed	not performed by mistake	Visit Schedule Compliance	Phone Call at 48h, Phone Call	18JUL2020
		Time field for ICF Version 6.0, dated on 26 JUN 2020 left blank by mistake. Therefore MEMO 03 Missing time ICF Version 6.0 was written.	By mistake time was missing on ICF Version 6.0, dated on 26 JUN 2020 for this Subject.	Other	Unscheduled Forms, Informed Consent	16JUL2020
	10171	Measurements (Body temp./Vital signs/ECG) not prior to Allocation	done by mistake	Visit Schedule Compliance	Visit 1, predose	16JUL2020
		Phone call was not performed	not performed by mistake	Visit Schedule Compliance	Phone Call at 48h, Phone Call	18JUL2020
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**Listing 16.2.1-2-1: Listing of protocol deviations - BNT162b1**

Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence	
20 µg Younger	10171	Time field for ICF Version 6.0, dated on 26 JUN 2020 left blank by mistake. Therefore MEMO 03 Missing time ICF Version 6.0 was written.	By mistake time was missing on ICF Version 6.0, dated on 26 JUN 2020 for this Subject.	Other	Unscheduled Forms, Informed Consent	16JUL2020	
	10172	Measurements (Body temp./Vital signs/ECG) not prior to Allocation	done by mistake	Visit Schedule Compliance	Visit 1, predose	16JUL2020	
		Phone call was not performed	not performed by mistake	Visit Schedule Compliance	Phone Call at 48h, Phone Call	18JUL2020	
		Time field for ICF Version 6.0, dated on 26 JUN 2020 left blank by mistake. Therefore MEMO 03 Missing time ICF Version 6.0 was written.	By mistake time was missing on ICF Version 6.0, dated on 26 JUN 2020 for this Subject.	Other	Unscheduled Forms, Informed Consent	16JUL2020	
	10173	Measurements (Body temp./Vital signs/ECG) not prior to Allocation	done by mistake	Visit Schedule Compliance	Visit 1, predose	16JUL2020	
		Phone call was not performed	not performed by mistake	Visit Schedule Compliance	Phone Call at 48h, Phone Call	18JUL2020	
		Time field for ICF Version 6.0, dated on 26 JUN 2020 left blank by mistake. Therefore MEMO 03 Missing time ICF Version 6.0 was written.	By mistake time was missing on ICF Version 6.0, dated on 26 JUN 2020 for this Subject.	Other	Unscheduled Forms, Informed Consent	16JUL2020	
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Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence	
20 µg Younger	10175	Measurements (Body temp./Vital signs/ECG) not prior to Allocation	done by mistake	Visit Schedule Compliance	Visit 1, predose	16JUL2020	
		Phone call was not performed	not performed by mistake	Visit Schedule Compliance	Phone Call at 48h, Phone Call	18JUL2020	
		Time field for ICF Version 6.0, dated on 26 JUN 2020 left blank by mistake. Therefore MEMO 03 Missing time ICF Version 6.0 was written.	By mistake time was missing on ICF Version 6.0, dated on 26 JUN 2020 for this Subject.	Other	Unscheduled Forms, Informed Consent	16JUL2020	
	10176	Measurements (Body temp./Vital signs/ECG) not prior to Allocation	done by mistake	Visit Schedule Compliance	Visit 1, predose	16JUL2020	
		Phone call was not performed	not performed by mistake	Visit Schedule Compliance	Phone Call at 48h, Phone Call	18JUL2020	
		Time field for ICF Version 6.0, dated on 26 JUN 2020 left blank by mistake. Therefore MEMO 03 Missing time ICF Version 6.0 was written.	By mistake time was missing on ICF Version 6.0, dated on 26 JUN 2020 for this Subject.	Other	Unscheduled Forms, Informed Consent	16JUL2020	
	10178	Measurements (Body temp./Vital signs/ECG) not prior to Allocation	done by mistake	Visit Schedule Compliance	Visit 1, predose	16JUL2020	
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Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
20 µg Younger	10178	Time field for ICF Version 6.0, dated on 26 JUN 2020 left blank by mistake. Therefore MEMO 03 Missing time ICF Version 6.0 was written.	By mistake time was missing on ICF Version 6.0, dated on 26 JUN 2020 for this Subject.	Other	Unscheduled Forms, Informed Consent	16JUL2020
	10179	Measurements (Body temp./Vital signs/ECG) not prior to Allocation	done by mistake	Visit Schedule Compliance	Visit 1, predose	16JUL2020
		Time field for ICF Version 6.0, dated on 26 JUN 2020 left blank by mistake. Therefore MEMO 03 Missing time ICF Version 6.0 was written.	By mistake time was missing on ICF Version 6.0, dated on 26 JUN 2020 for this Subject.	Other	Unscheduled Forms, Informed Consent	16JUL2020
	10181	Diary pages not returned and reviewed	Subject left the site earlier than planned	Visit Schedule Compliance	Visit 5, Diary - Local Reactions	13AUG2020
		Measurements (Body temp./Vital signs/ECG) not prior to Allocation	done by mistake	Visit Schedule Compliance	Visit 1, predose	16JUL2020
		Physical examination, assessment of local and systemic reactions not done	Subject left the site earlier than planned	Visit Schedule Compliance	Visit 5	13AUG2020
		The visit was performed outside study scheme	due to private reasons	Visit Schedule Compliance	Visit 8 (c2) (FU) / Visit 9 (a1, b1, b2) (FU)	14OCT2020
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**Listing 16.2.1-2-1: Listing of protocol deviations - BNT162b1**

Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence	
20 µg Younger	10181	Time field for ICF Version 6.0, dated on 26 JUN 2020 left blank by mistake. Therefore MEMO 03 Missing time ICF Version 6.0 was written.	By mistake time was missing on ICF Version 6.0, dated on 26 JUN 2020 for this Subject.	Other	Unscheduled Forms, Informed Consent	16JUL2020	
	10182	Time field for ICF Version 6.0, dated on 26 JUN 2020 left blank by mistake. Therefore MEMO 03 Missing time ICF Version 6.0 was written.	By mistake time was missing on ICF Version 6.0, dated on 26 JUN 2020 for this Subject.	Other	Unscheduled Forms, Informed Consent	16JUL2020	
	10183		Time field for ICF Version 6.0, dated on 26 JUN 2020 left blank by mistake. Therefore MEMO 03 Missing time ICF Version 6.0 was written.	By mistake time was missing on ICF Version 6.0, dated on 26 JUN 2020 for this Subject.	Other	Unscheduled Forms, Informed Consent	16JUL2020
			urine pregnancy testing performed	done by mistake	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Urine Pregnancy Test	09JUL2020
			urine pregnancy testing performed	Pregnancy test performed by mistake	Laboratory Data, ECG Data, Pregnancy Data	Visit 4, Urine Pregnancy Test	06AUG2020
30 µg Younger	10016	Assessment of local reaction at injection site was performed 4 min later than the allowed time window	logistic reason	Visit Schedule Compliance	Visit 1, Local Tolerability at Injection Site, 06 h a.v.	29APR2020	
		FSH Level was not determined.	done by mistake	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	23APR2020	
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Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
30 µg Younger	10016	Measurements (Body Temperature, Vital Signs, ECG) not prior to Allocation	done by mistake	Visit Schedule Compliance	Visit 1, predose	29APR2020
	10020	FSH Level was not determined.	Done by mistake.	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	24APR2020
		Measurements (Vital Signs, ECG) not prior to Allocation	done by mistake	Visit Schedule Compliance	Visit 1, predose	29APR2020
		The measurement was not performed in the scheduled timeframe.	logistic reason	Visit Schedule Compliance	Visit 1, Body Temperature, predose	29APR2020
	10031	The measurements were not performed in the scheduled timeframe	Visit 2 Day 2 will be postponed to day 3, Subject is unable to come into Unit due to Adverse Event	Visit Schedule Compliance	Visit 2	08MAY2020
	10043	Diary entries for Day 03.06.2020 for Local and Systemic Reactions are not available.	Missing entries	Other	Visit 5	03JUN2020
		FSH Level was not determined.	Done by mistake	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	28APR2020
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Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
30 µg Younger	10043	The measurements were not performed in the scheduled timeframe	Logistical reason	Visit Schedule Compliance	Visit 4, Vital Signs, 1h, 3h and 6h after	28MAY2020
		The measurements were not performed in the scheduled timeframe	Logistical reason	Visit Schedule Compliance	Visit 4, Body Temperature, 1h, 3h and 6h after	28MAY2020
		The measurements were not performed in the scheduled timeframe	Logistical reason	Visit Schedule Compliance	Visit 4, Local Tolerability at Injection Site, 1h, 3h and 6h after	28MAY2020
		Urine Pregnancy Test Performed	Done by Mistake	Laboratory Data, ECG Data, Pregnancy Data	Visit 4, Urine Pregnancy Test	28MAY2020
50 µg Younger	10050	FSH Level was not determined.	Done by mistake	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	05MAY2020
	10055	Diary entries for Day 09.06.2020 for Local and Systemic Reactions are not available.	Missing Entries	Other	Visit 5	09JUN2020
		FSH Level was not determined.	Done by mistake.	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	07MAY2020
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Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
50 µg Younger	10055	Urine Pregnancy Testing Performed	Done by Mistake	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Urine Pregnancy Test	07MAY2020
	10056	Assessment of local reaction at injection site was performed 7 min later than the allowed time window	due to logistic reason assessment was performed later	Visit Schedule Compliance	Visit 1, Local Tolerability at Injection Site, 6 h.a.v.	13MAY2020
		Diary entries for Day 09.06.2020 for Local and Systemic Reactions are not available.	Missing entries.	Other	Visit 5	09JUN2020
		FSH Level was not determined.	Done by mistake.	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	07MAY2020
		The planned activities were not performed in the scheduled timeframe	due to logistic reason phone call was performed earlier.	Visit Schedule Compliance	Phone Call at 48h	15MAY2020
	10059	Diary entries for Day 09.06.2020 for Local and Systemic Reactions are not available.	Missing entries	Other	Visit 5	09JUN2020
		FSH Level was not determined	Done by mistake.	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	07MAY2020
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Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
50 µg Younger	10059	The planned activities were not performed in the scheduled timeframe	Due to logistic reason phone call was performed earlier	Visit Schedule Compliance	Phone Call at 48h	15MAY2020
	10060	Diary entries for Day 09.06.2020 for Local and Systemic Reactions are not available.	Missing entries.	Other	Visit 5	09JUN2020
		Subject takes Novaminsulfon (oral, 1x1tbl. 500 mg)	Subject had lost his "take-home given Paracetamol tablets", \n so instead he took Novaminsulfon	Treatment Compliance	Unrelated Forms, Prior/Concomitant Medication/Therapy	14MAY2020
		The planned activities were not performed in the scheduled timeframe	due to logistic reason phone call was performed earlier.	Visit Schedule Compliance	Phone Call at 48h	15MAY2020
	10068	FSH Level was not determined.	Done by mistake.	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	08MAY2020
	10073	FSH Level was not determined.	Done by mistake.	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	11MAY2020
60 µg Younger	10075	FSH Level was not determined.	Done by mistake.	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	11MAY2020
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**Listing 16.2.1-2-1: Listing of protocol deviations - BNT162b1**

Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
60 µg Younger	10076	FSL level was not determined.	Done by mistake.	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	11MAY2020
	10083	FSH level was not determined.	Done by mistake.	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	12MAY2020
	10089	FSH Level was not determined.	Done by mistake.	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	12MAY2020
	10103	FSH Level was not determined.	Done by mistake.	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	14MAY2020
	10104	The planned activities were not performed in the scheduled timeframe	Telephone call earlier due to logistic reason	Visit Schedule Compliance	Phone Call at 48h	22MAY2020
10 µg Older	10274	Check was performed too early	done by mistake	Visit Schedule Compliance	Visit 1, Local Tolerability at Injection Site, 3 h a.v.	27AUG2020
		Check was performed too early	done by mistake	Visit Schedule Compliance	Visit 1, Systemic Events Assessment, 3 h a.v.	27AUG2020
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Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

**Listing 16.2.1-2-1: Listing of protocol deviations - BNT162b1**

Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
10 µg Older	10274	wrong entry for pulse rate (012), so value is unknown	wrong entry by mistake	Other	Visit 6 (a1, b1, b2, c2P/B) / (c2) (EoT), Vital Signs	08OCT2020
	10282	no detailed information beside date/day reported in diary on day 3-7	subject forgot to enter data	Treatment Compliance	Unrelated Forms, Diary - Local Reactions, Day 3-7	22AUG2020
		urine sample was given outside the scheduled time frame of +/-2 h of vaccination	subject couldn't wait any longer to give urine.	Visit Schedule Compliance	Visit 2, Urine Sampling for Urinalysis	21AUG2020
	10292	items for nausea and vomiting not assessed	done by mistake	Treatment Compliance	Visit 5, Systemic Events Assessment	24SEP2020
		wrong entry for pulse rate (011), so value is unknown	wrong entry by mistake	Other	Visit 6 (a1, b1, b2, c2P/B) / (c2) (EoT), Vital Signs	08OCT2020
	10298	measurements performed, but values not documented	values not entered by mistake	Other	Visit 6 (a1, b1, b2, c2P/B) / (c2) (EoT), Vital Signs	08OCT2020
20 µg Older	20234	The PCR test was repeated at Visit1 before the predose recording, because at Visit -1 the test was not evaluable	the first test was failed	Laboratory Data, ECG Data, Pregnancy Data	Visit 1, Oral Swipe for SARS-CoV-2 Testing	09SEP2020
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Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

**Listing 16.2.1-2-1: Listing of protocol deviations - BNT162b1**

Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
20 µg Older	20239	day 28 - data missing	has not been filled in by subject	Other	Visit 5, Diary - Local Reactions, day 28	08OCT2020
30 µg Older	10351	By mistake, allocation was done before the alcohol breath testing	done by mistake	Visit Schedule Compliance	Visit 1, Allocation	25SEP2020
		diary entries for local reactions are entered for only 5 consecutive days after V4 (until day 27)	done by mistake	Treatment Compliance	Unrelated Forms, Diary - Local Reactions	21OCT2020
		diary entries for systemic reactions are entered for only 5 consecutive days after V4 (until day 27)	done by mistake	Treatment Compliance	Unrelated Forms, Diary - Systemic Reactions	21OCT2020
	10358	Allocation was done prior to predose measurements (vital signs, body temperature, ecg)	done by mistake	Visit Schedule Compliance	Visit 1, Allocation	23SEP2020
		Measurements (Body temp./Vital signs/ECG) not prior to allocation	done by mistake	Visit Schedule Compliance	Visit 1, Vital Signs, Predose	23SEP2020
	10360	predefined timeframe of 30 minutes between the vaccination of subjects was not adhered. (done after 29 minutes)	done by mistake 1 min. too early	Treatment Compliance	Visit 1, Administration	23SEP2020
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Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

**Listing 16.2.1-2-1: Listing of protocol deviations - BNT162b1**

Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
30 µg Older	10362	No modules except for fever were ticked, although assessments were done. No symptoms were reported.	done by mistake	Other	Visit 4, Systemic Events Assessment, 3 h a.v.	16OCT2020
	10364	diary entries for systemic reactions are entered for only 5 consecutive days after V4 (until day 27)	done by mistake	Treatment Compliance	Unrelated Forms, Diary - Systemic Reactions	21OCT2020
		urine sample was given outside the scheduled time frame of +/-2 h of vaccination	subject couldn't wait any longer to give urine.	Visit Schedule Compliance	Visit 2, Urine Sampling for Urinalysis	26SEP2020
	10366	urine sample was given outside the scheduled time frame of +/-2 h of vaccination	subject couldn't wait any longer to give urine.	Visit Schedule Compliance	Visit 2, Urine Sampling for Urinalysis	24SEP2020
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Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

**Listing 16.2.1-2-3: Listing of protocol deviations - BNT162b2**

Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
1 µg Younger	20158	No entries available. The test Person appears on day 26. The Diary was collected	logistic reason	Visit Schedule Compliance	Visit 5, Diary - Local Reactions, Day 29	07AUG2020
		No entries available. The test Person appears on day 26. The Diary was collected	logistic reason	Visit Schedule Compliance	Visit 5, Diary - Systemic Reactions, Day 29	07AUG2020
		the action took place 20 minutes later, 5 minutes outside the time range	logistic reason	Visit Schedule Compliance	Visit 1, Systemic Events Assessment, 1h	13JUL2020
		the action took place 20 minutes later, 5 minutes outside the time range	logistic reason	Visit Schedule Compliance	Visit 1, Local Tolerability at Injection Site, 1h	13JUL2020
	20164	an additional Control test on visit 4 drior to vaccination	The test person returned from a corona endangered area 4 days ago	Other	Visit 4, Oral Swipe for SARS-CoV-2 Testing	03AUG2020
3 µg Younger	20197	Body temperature measurement is 2 minutes out of range of tolerance ( 2 minutes too early)	staff error	Visit Schedule Compliance	Visit 2, Body Temperature, 24 h	29JUL2020
	20204	All measures are outside the 2h timedeviation	The subject had time problems	Visit Schedule Compliance	Visit 2	01AUG2020
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Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

**Listing 16.2.1-2-3: Listing of protocol deviations - BNT162b2**

Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
10 µg Younger	20105	Assessment not done because the CRF was not available at that time	no actual CRF file available	Visit Schedule Compliance	Visit 5, Systemic Events Assessment, D29	14JUL2020
	20110	FSH is missing, subject has a tubal ligation	not specified	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Blood Samples for Safety Lab	19MAY2020
		centrifugation Glucose 8 minutes too late	staff error	Laboratory Data, ECG Data, Pregnancy Data	Visit 3, Blood Samples for Safety Lab	22JUN2020
	20111	The test person had rhinitis on day 22 and could not be vaccinated. The vaccination was delayed on day 28.	rhinititis	Medical History and Concomitant Diseases	Visit 4, Administration	15JUL2020
		The visit 5 day 29 was moved to day 36.	displaced booster	Treatment Compliance	Visit 5	23JUL2020
	20116	Subject cancelled booster	due to feeling cold	Treatment Compliance	Visit 4, D22	09JUL2020
		Visit 6 was skipped because subject prematurely terminated the Trial, so EoT Visit 7 was performed earlier than planned.	the subject ends the study by this day	Visit Schedule Compliance	Visit 6 (a1, b1, b2, c2P/B) / (c2) (EoT), D43	30JUL2020
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Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.



**Listing 16.2.1-2-3: Listing of protocol deviations - BNT162b2**

Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
20 µg Younger	20159	The subject moved his visit 6 by 5 days. That's one day too many	time problem by volunteer	Visit Schedule Compliance	Visit 6 (a1, b1, b2) / (c2) (EoT)	07AUG2020
	20175	Phone Call not performed	staff error	Visit Schedule Compliance	Phone Call at 48h, Phone Call	09JUL2020
	20180	The consent form for "Pharmagenomic Examination HLA" was signed 3 min before the consent form version 6.0 Protocol Version 7.0, June 26, 2020	staff error	Other	Visit 1, Informed Consent + Blood Sampling for HLA typing	13JUL2020
	20183	Body temperature was measured outside the allowed timeframe ( 13 min too early)	staff error	Laboratory Data, ECG Data, Pregnancy Data	Visit 2, Body Temperature, 24 h (+/- 2h)	14JUL2020
		The consent form for "Pharmagenomic Examination HLA" was signed 2 min before the consent form version 6.0, June 26, 2020	staff error	Other	Visit 1, Informed Consent + Blood Sampling for HLA typing	13JUL2020
30 µg Younger	20149	centrifugation 13 minutes too early	Staff error	Laboratory Data, ECG Data, Pregnancy Data	Visit 1, Blood Samples for Immunogenicity	22JUN2020
	20150	Because of private appointments of the subject, this appointment is cancelled completely.	time problem by volunteer	Visit Schedule Compliance	Visit 6 (a1, b1, b2) / (c2) (EoT), all	04AUG2020
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**Listing 16.2.1-2-3: Listing of protocol deviations - BNT162b2**

Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
30 µg Younger	20155	Subject removed from the room unmasked before the measurements, so the measures were taken a few minutes too late	mistake by subject	Treatment Compliance	Visit 4, Vital Signs, D22 (1h after Vaccination)	14JUL2020
10 µg Older	10261	Dose was given in two parts	Due to mix-up with previous CTP the wrong dose was prepared (3µg). Shortly after administration the mistake was recognized and the remaining 7 µg have been administered after clarification with the sp	Treatment Compliance	Visit 1, Administration	14AUG2020
		Phone call was not performed in the scheduled time frame	call was too late due to volunteers problems with its mobile phone	Visit Schedule Compliance	Phone Call at 48h (a1, b1, b2, c2P/B), Phone Call	07SEP2020
	10263	predefined timeframe of 30 minutes between the vaccination of subjects was not adhered.	Previous subject (0261) was dosed in two parts, only 1st vaccination time of this subject was regarded.	Treatment Compliance	Visit 1, Administration	14AUG2020
		urine sample was given outside the scheduled time frame of +/-2 h of vaccination	subject couldn't wait any longer to give urine.	Visit Schedule Compliance	Visit 2, Urine Sampling for Urinalysis	15AUG2020
	10265	Check was performed too late	due to emergency call of the checking physician	Visit Schedule Compliance	Visit 4, Local Tolerability at Injection Site, 1 h a.v.	08SEP2020
		Check was performed too late	due to emergency call of the checking physician	Visit Schedule Compliance	Visit 4, Systemic Events Assessment, 1 h a.v.	08SEP2020
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**Listing 16.2.1-2-3: Listing of protocol deviations - BNT162b2**

Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
10 µg Older	10265	Vital signs and body temperature were performed outside the allowed time window of +/-15 min	done by mistake	Visit Schedule Compliance	Visit 4, Vital Signs, 1 h a.v.	08SEP2020
	10267	Body temperature was performed outside the allowed time window of +/-15 min	done by mistake	Visit Schedule Compliance	Visit 4, Body Temperature, 3 h a.v.	08SEP2020
		Body temperature was performed outside the allowed time window of +/-15 min	done by mistake	Visit Schedule Compliance	Visit 4, Body Temperature, 6 h a.v.	08SEP2020
	10268	Urine pregnancy test performed	done by mistake	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Urine Pregnancy Test	05AUG2020
		Vital signs and body temperature were performed outside the allowed time window of +/-15 min	done by mistake	Visit Schedule Compliance	Visit 4, Vital Signs, 1 h a.v.	08SEP2020
	10276	measurements performed, but values not documented	values not entered by mistake	Other	Visit 2, Physical Examination	21AUG2020
	10299	Vital Signs and body temperature: measurements performed, but values not documented	values not entered by mistake	Other	Visit 3	27AUG2020
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**Listing 16.2.1-2-3: Listing of protocol deviations - BNT162b2**

Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
20 µg Older	20225	The blood can't quite be distributed	Not enough material	Laboratory Data, ECG Data, Pregnancy Data	Visit 3, Blood Samples for Immunogenicity	02SEP2020
30 µg Older	10272	diary entries for local reactions are entered for only 4 consecutive days after V4 (day 22-25)	done by mistake	Treatment Compliance	Visit 5, Diary - Local Reactions	29SEP2020
		diary entries for systemic reactions are entered for only 5 consecutive days after V4 (day 22-26)	done by mistake	Treatment Compliance	Visit 5, Diary - Systemic Reactions	29SEP2020
	10303	Urine pregnancy testing performed	done by mistake	Laboratory Data, ECG Data, Pregnancy Data	Visit 1, Urine Pregnancy Test	04SEP2020
		diary entries for local and systemic reactions are entered for only 5 consecutive days after V4 (day 22-26)	done by mistake, cause Visit 5 was scheduled and performed for day 27, so no entries were at site by subject itself	Treatment Compliance	Visit 5, Diary - Local Reactions	30SEP2020
		diary entries for local and systemic reactions are entered for only 5 consecutive days after V4 (day 22-26)	done by mistake, cause Visit 5 was scheduled and performed for day 27, so no entries were at site by subject itself	Treatment Compliance	Visit 5, Diary - Systemic Reactions	30SEP2020
	10305	No CMI samples taken	logistic reasons	Laboratory Data, ECG Data, Pregnancy Data	Visit 5, Blood Samples for CMI	02OCT2020
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**Listing 16.2.1-2-3: Listing of protocol deviations - BNT162b2**

Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
30 µg Older	10306	Urine pregnancy testing performed	done by mistake	Laboratory Data, ECG Data, Pregnancy Data	Visit 0, Urine Pregnancy Test	21AUG2020
	10308	Measurement performed but value not documented	Value not entered by mistake	Visit Schedule Compliance	Visit 4, Body Temperature, 6 h a.v.	24SEP2020
		diary entries for local and systemic reactions are entered for only 5 consecutive days after V4 (day 22-26)	done by mistake, cause Visit 5 was scheduled and performed for day 27, so no entries were at site by subject itself	Treatment Compliance	Visit 5, Diary - Local Reactions	30SEP2020
		diary entries for local and systemic reactions are entered for only 5 consecutive days after V4 (day 22-26)	done by mistake, cause Visit 5 was scheduled and performed for day 27, so no entries were at site by subject itself	Treatment Compliance	Visit 5, Diary - Systemic Reactions	30SEP2020
	10310	Body temperature was performed outside the allowed time window of +/- 15 min	done by mistake	Visit Schedule Compliance	Visit 4, Body Temperature, 1 h a.v.	23SEP2020
	10319	Urine pregnancy testing performed	done by mistake	Laboratory Data, ECG Data, Pregnancy Data	Visit 1, Urine Pregnancy Test	04SEP2020
		diary entries for local and systemic reactions are entered for only 5 consecutive days after after V4 (day 22-26)	done by mistake	Treatment Compliance	Visit 5, Diary - Local Reactions	30SEP2020
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**Listing 16.2.1-2-3: Listing of protocol deviations - BNT162b2**

Safety set

Dose group	Subject number	Description	Reason for deviation	Coded term	Reference	Date of occurrence
30 µg Older	10319	diary entries for local and systemic reactions are entered for only 5 consecutive days after V4 (day 22-26)	done by mistake	Treatment Compliance	Visit 5, Diary - Systemic Reactions	30SEP2020
	10323	Urine pregnancy test was performed	done by mistake	Laboratory Data, ECG Data, Pregnancy Data	Visit 1, Urine Pregnancy Test	04SEP2020
		diary entries for local and systemic reactions are entered for only 5 consecutive days after V4 (day 22-26)	done by mistake, cause Visit 5 was scheduled and performed for day 27, so no entries were at site by subject itself	Treatment Compliance	Visit 5, Diary - Local Reactions	30SEP2020
		diary entries for local and systemic reactions are entered for only 5 consecutive days after V4 (day 22-26)	done by mistake, cause Visit 5 was scheduled and performed for day 27, so no entries were at site by subject itself	Treatment Compliance	Visit 5, Diary - Systemic Reactions	30SEP2020
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