

Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 1 µg Younger | 10015 | 29APR2020 23:00 | Pain | Mild | 0 | | 29APR2020 9:23 |
| | | 29APR2020 23:00 | Tenderness | Moderate | 0 | | 29APR2020 9:23 |
| | | 20MAY2020 23:00 | Pain | Mild | 21 | 0 | 29APR2020 9:23 |
| | 10018 | 29APR2020 | Pain | Mild | 0 | | 29APR2020 9:53 |
| | | 29APR2020 | Tenderness | Moderate | 0 | | 29APR2020 9:53 |
| | | 20MAY2020 23:00 | Pain | Mild | 21 | 0 | 29APR2020 9:53 |
| | | 20MAY2020 23:00 | Tenderness | Mild | 21 | 0 | 29APR2020 9:53 |
| | 10025 | 26MAY2020 22:00 | Pain | Mild | 21 | 0 | 05MAY2020 9:06 |
| | | 26MAY2020 22:00 | Tenderness | Mild | 21 | 0 | 05MAY2020 9:06 |
| | 10033 | 05MAY2020 20:00 | Tenderness | Mild | 0 | | 05MAY2020 10:03 |
| | | 28MAY2020 20:00 | Tenderness | Mild | 23 | 2 | 05MAY2020 10:03 |
| | 10040 | 08MAY2020 20:31 | Pain | Mild | 0 | | 08MAY2020 8:51 |
| | | 08MAY2020 20:31 | Tenderness | Mild | 0 | | 08MAY2020 8:51 |
| | | 09MAY2020 21:20 | Pain | Mild | 1 | | 08MAY2020 8:51 |
| | | 09MAY2020 21:20 | Tenderness | Mild | 1 | | 08MAY2020 8:51 |
| 30MAY2020 21:18 | | Pain | Moderate | 22 | 1 | 08MAY2020 8:51 | |
| 30MAY2020 21:18 | | Tenderness | Severe | 22 | 1 | 08MAY2020 8:51 | |
| 30MAY2020 21:18 | | Induration/Swelling | Moderate | 22 | 1 | 08MAY2020 8:51 | |
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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--------------|----------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 1 µg Younger | 10040 | 31MAY2020 21:04 | Pain | Severe | 23 | 2 | 08MAY2020 8:51 |
| | | 31MAY2020 21:04 | Tenderness | Severe | 23 | 2 | 08MAY2020 8:51 |
| | | 01JUN2020 21:10 | Pain | Moderate | 24 | 3 | 08MAY2020 8:51 |
| | | 01JUN2020 21:10 | Tenderness | Moderate | 24 | 3 | 08MAY2020 8:51 |
| | | 02JUN2020 21:00 | Pain | Severe | 25 | 4 | 08MAY2020 8:51 |
| | | 02JUN2020 21:00 | Tenderness | Severe | 25 | 4 | 08MAY2020 8:51 |
| | | 03JUN2020 21:15 | Pain | Moderate | 26 | 5 | 08MAY2020 8:51 |
| | | 03JUN2020 21:15 | Tenderness | Moderate | 26 | 5 | 08MAY2020 8:51 |
| | 10041 | 08MAY2020 20:25 | Pain | Mild | 0 | | 08MAY2020 9:06 |
| | | 08MAY2020 20:25 | Tenderness | Mild | 0 | | 08MAY2020 9:06 |
| | | 09MAY2020 21:20 | Pain | Mild | 1 | | 08MAY2020 9:06 |
| | | 09MAY2020 21:20 | Tenderness | Mild | 1 | | 08MAY2020 9:06 |
| | | 29MAY2020 22:10 | Pain | Mild | 21 | 0 | 08MAY2020 9:06 |
| | | 29MAY2020 22:10 | Tenderness | Severe | 21 | 0 | 08MAY2020 9:06 |
| | | 30MAY2020 21:18 | Pain | Moderate | 22 | 1 | 08MAY2020 9:06 |
| | | 30MAY2020 21:18 | Tenderness | Severe | 22 | 1 | 08MAY2020 9:06 |
| | | 30MAY2020 21:18 | Induration/Swelling | Moderate | 22 | 1 | 08MAY2020 9:06 |
| | | 31MAY2020 21:04 | Pain | Moderate | 23 | 2 | 08MAY2020 9:06 |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--------------|----------------|---|----------------|---------------------|---|---|---------------------------------|
| 1 µg Younger | 10041 | 31MAY2020 21:04 | Tenderness | Moderate | 23 | 2 | 08MAY2020 9:06 |
| | | 01JUN2020 21:13 | Pain | Mild | 24 | 3 | 08MAY2020 9:06 |
| | 10052 | 08MAY2020 23:00 | Tenderness | Mild | 0 | | 08MAY2020 9:51 |
| | | 09MAY2020 23:10 | Tenderness | Mild | 1 | | 08MAY2020 9:51 |
| | | 02JUN2020 | Pain | Moderate | 25 | 4 | 08MAY2020 9:51 |
| | | 02JUN2020 | Tenderness | Moderate | 25 | 4 | 08MAY2020 9:51 |
| 3 µg Younger | 10170 | 31JUL2020 20:00 | Pain | Mild | 0 | | 31JUL2020 8:00 |
| | | 31JUL2020 20:00 | Tenderness | Mild | 0 | | 31JUL2020 8:00 |
| | | 01AUG2020 20:05 | Tenderness | Mild | 1 | | 31JUL2020 8:00 |
| | | 21AUG2020 20:04 | Tenderness | Mild | 21 | 0 | 31JUL2020 8:00 |
| | 10194 | 22JUL2020 21:15 | Pain | Mild | 0 | | 22JUL2020 8:00 |
| | | 22JUL2020 21:15 | Tenderness | Mild | 0 | | 22JUL2020 8:00 |
| | | 23JUL2020 21:45 | Pain | Mild | 1 | | 22JUL2020 8:00 |
| | | 23JUL2020 21:45 | Tenderness | Mild | 1 | | 22JUL2020 8:00 |
| | | 12AUG2020 22:15 | Tenderness | Mild | 21 | 0 | 22JUL2020 8:00 |
| | | 13AUG2020 21:45 | Tenderness | Mild | 22 | 1 | 22JUL2020 8:00 |
| | | 14AUG2020 22:00 | Tenderness | Mild | 23 | 2 | 22JUL2020 8:00 |
| | | 17AUG2020 22:00 | Pain | Mild | 26 | 5 | 22JUL2020 8:00 |
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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---|----------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 3 µg Younger | 10194 | 17AUG2020 22:00 | Tenderness | Mild | 26 | 5 | 22JUL2020 8:00 |
| | | 17AUG2020 22:00 | Erythema/Redness | Mild | 26 | 5 | 22JUL2020 8:00 |
| | | 17AUG2020 22:00 | Induration/Swelling | Mild | 26 | 5 | 22JUL2020 8:00 |
| | 10204 | 12AUG2020 21:45 | Pain | Mild | 21 | 0 | 22JUL2020 8:45 |
| | | 12AUG2020 21:45 | Tenderness | Mild | 21 | 0 | 22JUL2020 8:45 |
| | | 13AUG2020 22:00 | Tenderness | Mild | 22 | 1 | 22JUL2020 8:45 |
| | | 17AUG2020 21:40 | Pain | Mild | 26 | 5 | 22JUL2020 8:45 |
| | | 17AUG2020 21:40 | Tenderness | Mild | 26 | 5 | 22JUL2020 8:45 |
| | 10212 | 22JUL2020 20:30 | Tenderness | Mild | 0 | | 22JUL2020 9:15 |
| | | 23JUL2020 21:30 | Tenderness | Mild | 1 | | 22JUL2020 9:15 |
| | | 24JUL2020 20:30 | Tenderness | Mild | 2 | | 22JUL2020 9:15 |
| | | 25JUL2020 20:45 | Tenderness | Mild | 3 | | 22JUL2020 9:15 |
| | | 26JUL2020 20:40 | Tenderness | Mild | 4 | | 22JUL2020 9:15 |
| | | 27JUL2020 20:45 | Tenderness | Mild | 5 | | 22JUL2020 9:15 |
| | | 12AUG2020 21:30 | Tenderness | Mild | 21 | 0 | 22JUL2020 9:15 |
| 13AUG2020 20:00 | | Tenderness | Mild | 22 | 1 | 22JUL2020 9:15 | |
| 14AUG2020 20:00 | | Tenderness | Mild | 23 | 2 | 22JUL2020 9:15 | |
| 15AUG2020 22:30 | Tenderness | Mild | 24 | 3 | 22JUL2020 9:15 | | |
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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--------------|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 3 µg Younger | 10212 | 16AUG2020 21:00 | Tenderness | Mild | 25 | 4 | 22JUL2020 9:15 |
| | | 17AUG2020 | Tenderness | Mild | 26 | 5 | 22JUL2020 9:15 |
| | 10226 | 31JUL2020 20:00 | Pain | Mild | 0 | | 31JUL2020 8:45 |
| | | 31JUL2020 20:00 | Tenderness | Mild | 0 | | 31JUL2020 8:45 |
| | | 01AUG2020 20:00 | Pain | Moderate | 1 | | 31JUL2020 8:45 |
| | | 01AUG2020 20:00 | Tenderness | Moderate | 1 | | 31JUL2020 8:45 |
| | | 02AUG2020 20:00 | Pain | Mild | 2 | | 31JUL2020 8:45 |
| | | 02AUG2020 20:00 | Tenderness | Mild | 2 | | 31JUL2020 8:45 |
| | | 03AUG2020 20:00 | Tenderness | Mild | 3 | | 31JUL2020 8:45 |
| | | 21AUG2020 20:00 | Pain | Moderate | 21 | 0 | 31JUL2020 8:45 |
| | | 21AUG2020 20:00 | Tenderness | Moderate | 21 | 0 | 31JUL2020 8:45 |
| | | 22AUG2020 20:00 | Pain | Moderate | 22 | 1 | 31JUL2020 8:45 |
| | | 22AUG2020 20:00 | Tenderness | Mild | 22 | 1 | 31JUL2020 8:45 |
| | | 23AUG2020 20:00 | Pain | Mild | 23 | 2 | 31JUL2020 8:45 |
| | | 23AUG2020 20:00 | Tenderness | Mild | 23 | 2 | 31JUL2020 8:45 |
| | | 24AUG2020 20:00 | Tenderness | Mild | 24 | 3 | 31JUL2020 8:45 |
| | 10227 | 31JUL2020 18:00 | Tenderness | Mild | 0 | | 31JUL2020 9:15 |
| | | 01AUG2020 18:00 | Tenderness | Mild | 1 | | 31JUL2020 9:15 |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|---------------|---|-------------------------|-----------------|---------------------|---|---|---------------------------------|----------------|
| 10 µg Younger | 10001 | 15MAY2020 20:00 | Tenderness | Mild | 21 | 0 | 24APR2020 10:15 | |
| | 10003 | 29APR2020 19:10 | Pain | Mild | 1 | | 28APR2020 8:30 | |
| | | 29APR2020 19:10 | Tenderness | Mild | 1 | | 28APR2020 8:30 | |
| | | 19MAY2020 20:35 | Pain | Mild | 21 | 0 | 28APR2020 8:30 | |
| | | 19MAY2020 20:35 | Tenderness | Mild | 21 | 0 | 28APR2020 8:30 | |
| | | 20MAY2020 20:25 | Pain | Mild | 22 | 1 | 28APR2020 8:30 | |
| | | 20MAY2020 20:25 | Tenderness | Mild | 22 | 1 | 28APR2020 8:30 | |
| | | 21MAY2020 20:30 | Tenderness | Mild | 23 | 2 | 28APR2020 8:30 | |
| | | 22MAY2020 20:15 | Tenderness | Mild | 24 | 3 | 28APR2020 8:30 | |
| | | 23MAY2020 20:20 | Tenderness | Mild | 25 | 4 | 28APR2020 8:30 | |
| | | 24MAY2020 20:25 | Tenderness | Mild | 26 | 5 | 28APR2020 8:30 | |
| | | 25MAY2020 20:10 | Tenderness | Mild | 27 | 6 | 28APR2020 8:30 | |
| | | 26MAY2020 20:15 | Tenderness | Mild | 28 | 7 | 28APR2020 8:30 | |
| | | 10004 | 24APR2020 22:15 | Tenderness | Mild | 0 | | 24APR2020 9:15 |
| | 25APR2020 21:00 | | Tenderness | Mild | 1 | | 24APR2020 9:15 | |
| | 15MAY2020 21:30 | | Pain | Mild | 21 | 0 | 24APR2020 9:15 | |
| | 15MAY2020 21:30 | | Tenderness | Mild | 21 | 0 | 24APR2020 9:15 | |
| | 16MAY2020 22:15 | | Pain | Mild | 22 | 1 | 24APR2020 9:15 | |
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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 10 µg Younger | 10004 | 16MAY2020 22:15 | Tenderness | Mild | 22 | 1 | 24APR2020 9:15 |
| | | 17MAY2020 23:15 | Pain | Mild | 23 | 2 | 24APR2020 9:15 |
| | | 17MAY2020 23:15 | Tenderness | Mild | 23 | 2 | 24APR2020 9:15 |
| | | 18MAY2020 23:00 | Pain | Mild | 24 | 3 | 24APR2020 9:15 |
| | | 18MAY2020 23:00 | Tenderness | Mild | 24 | 3 | 24APR2020 9:15 |
| | 10005 | 24APR2020 21:00 | Tenderness | Moderate | 0 | | 24APR2020 11:15 |
| | | 25APR2020 19:30 | Tenderness | Moderate | 1 | | 24APR2020 11:15 |
| | | 15MAY2020 19:00 | Pain | Mild | 21 | 0 | 24APR2020 11:15 |
| | | 15MAY2020 19:00 | Tenderness | Mild | 21 | 0 | 24APR2020 11:15 |
| | | 16MAY2020 19:00 | Pain | Mild | 22 | 1 | 24APR2020 11:15 |
| | | 16MAY2020 19:00 | Tenderness | Mild | 22 | 1 | 24APR2020 11:15 |
| | 10006 | 29APR2020 22:00 | Pain | Mild | 1 | | 28APR2020 9:00 |
| | | 29APR2020 22:00 | Tenderness | Mild | 1 | | 28APR2020 9:00 |
| | | 19MAY2020 22:00 | Tenderness | Mild | 21 | 0 | 28APR2020 9:00 |
| | | 20MAY2020 22:00 | Tenderness | Mild | 22 | 1 | 28APR2020 9:00 |
| | 10007 | 23APR2020 20:00 | Pain | Mild | 0 | | 23APR2020 11:08 |
| | | 24APR2020 9:10 | Pain | Mild | 1 | | 23APR2020 11:08 |
| | | 24APR2020 9:10 | Tenderness | Mild | 1 | | 23APR2020 11:08 |
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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 10 µg Younger | 10007 | 25APR2020 9:00 | Pain | Mild | 2 | | 23APR2020 11:08 |
| | | 26APR2020 20:00 | Pain | Mild | 3 | | 23APR2020 11:08 |
| | | 27APR2020 20:00 | Pain | Mild | 4 | | 23APR2020 11:08 |
| | | 28APR2020 20:00 | Pain | Mild | 5 | | 23APR2020 11:08 |
| | | 14MAY2020 | Pain | Mild | 21 | 0 | 23APR2020 11:08 |
| | | 14MAY2020 | Tenderness | Moderate | 21 | 0 | 23APR2020 11:08 |
| | | 15MAY2020 20:00 | Pain | Moderate | 22 | 1 | 23APR2020 11:08 |
| | | 15MAY2020 20:00 | Tenderness | Mild | 22 | 1 | 23APR2020 11:08 |
| | | 15MAY2020 20:00 | Induration/Swelling | Mild | 22 | 1 | 23APR2020 11:08 |
| | | 16MAY2020 20:00 | Pain | Mild | 23 | 2 | 23APR2020 11:08 |
| | | 16MAY2020 20:00 | Tenderness | Mild | 23 | 2 | 23APR2020 11:08 |
| | | 17MAY2020 20:00 | Pain | Mild | 24 | 3 | 23APR2020 11:08 |
| | | 17MAY2020 20:00 | Tenderness | Mild | 24 | 3 | 23APR2020 11:08 |
| | | 18MAY2020 20:00 | Pain | Mild | 25 | 4 | 23APR2020 11:08 |
| | | 18MAY2020 20:00 | Tenderness | Mild | 25 | 4 | 23APR2020 11:08 |
| | 10008 | 28APR2020 22:00 | Tenderness | Moderate | 0 | | 28APR2020 9:30 |
| | | 29APR2020 22:00 | Tenderness | Mild | 1 | | 28APR2020 9:30 |
| | | 19MAY2020 22:00 | Tenderness | Mild | 21 | 0 | 28APR2020 9:30 |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|---------------|---|-------------------------|-----------------|---------------------|---|---|---------------------------------|-----------------|
| 10 µg Younger | 10008 | 20MAY2020 22:00 | Tenderness | Mild | 22 | 1 | 28APR2020 9:30 | |
| | | 21MAY2020 22:00 | Tenderness | Mild | 23 | 2 | 28APR2020 9:30 | |
| | 10009 | 28APR2020 21:00 | Pain | Mild | 0 | | 28APR2020 10:00 | |
| | | 28APR2020 21:00 | Tenderness | Mild | 0 | | 28APR2020 10:00 | |
| | | 29APR2020 20:30 | Tenderness | Mild | 1 | | 28APR2020 10:00 | |
| | | 30APR2020 20:00 | Tenderness | Mild | 2 | | 28APR2020 10:00 | |
| | | 19MAY2020 22:00 | Pain | Mild | 21 | 0 | 28APR2020 10:00 | |
| | | 19MAY2020 22:00 | Tenderness | Mild | 21 | 0 | 28APR2020 10:00 | |
| | | 20MAY2020 19:00 | Pain | Mild | 22 | 1 | 28APR2020 10:00 | |
| | | 20MAY2020 19:00 | Tenderness | Mild | 22 | 1 | 28APR2020 10:00 | |
| | | 21MAY2020 19:00 | Tenderness | Mild | 23 | 2 | 28APR2020 10:00 | |
| | | 10010 | 25APR2020 18:15 | Pain | Severe | 1 | | 24APR2020 12:15 |
| | 25APR2020 18:15 | | Tenderness | Severe | 1 | | 24APR2020 12:15 | |
| | 26APR2020 18:15 | | Pain | Moderate | 2 | | 24APR2020 12:15 | |
| | 26APR2020 18:15 | | Tenderness | Moderate | 2 | | 24APR2020 12:15 | |
| | 27APR2020 18:15 | | Pain | Moderate | 3 | | 24APR2020 12:15 | |
| | 27APR2020 18:15 | | Tenderness | Moderate | 3 | | 24APR2020 12:15 | |
| | 28APR2020 18:30 | | Pain | Moderate | 4 | | 24APR2020 12:15 | |
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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 10 µg Younger | 10010 | 28APR2020 18:30 | Tenderness | Moderate | 4 | | 24APR2020 12:15 |
| | | 29APR2020 18:30 | Pain | Moderate | 5 | | 24APR2020 12:15 |
| | | 29APR2020 18:30 | Tenderness | Moderate | 5 | | 24APR2020 12:15 |
| | | 30APR2020 18:15 | Pain | Mild | 6 | | 24APR2020 12:15 |
| | | 30APR2020 18:15 | Tenderness | Mild | 6 | | 24APR2020 12:15 |
| | | 01MAY2020 18:45 | Pain | Mild | 7 | | 24APR2020 12:15 |
| | | 01MAY2020 18:45 | Tenderness | Mild | 7 | | 24APR2020 12:15 |
| | | 02MAY2020 19:00 | Pain | Mild | 8 | | 24APR2020 12:15 |
| | | 02MAY2020 19:00 | Tenderness | Mild | 8 | | 24APR2020 12:15 |
| | 10011 | 25APR2020 6:30 | Pain | Mild | 1 | | 24APR2020 13:15 |
| | | 25APR2020 6:30 | Tenderness | Mild | 1 | | 24APR2020 13:15 |
| | | 26APR2020 6:15 | Tenderness | Mild | 2 | | 24APR2020 13:15 |
| | | 15MAY2020 22:00 | Pain | Mild | 21 | 0 | 24APR2020 13:15 |
| | | 15MAY2020 22:00 | Tenderness | Mild | 21 | 0 | 24APR2020 13:15 |
| | | 16MAY2020 22:00 | Pain | Mild | 22 | 1 | 24APR2020 13:15 |
| | | 16MAY2020 22:00 | Tenderness | Mild | 22 | 1 | 24APR2020 13:15 |
| | 10017 | 28APR2020 22:00 | Tenderness | Moderate | 0 | | 28APR2020 10:30 |
| | | 29APR2020 20:43 | Tenderness | Moderate | 1 | | 28APR2020 10:30 |
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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 10 µg Younger | 10017 | 19MAY2020 22:00 | Pain | Mild | 21 | 0 | 28APR2020 10:30 |
| 20 µg Younger | 10151 | 16JUL2020 18:00 | Pain | Mild | 0 | | 16JUL2020 8:00 |
| | | 16JUL2020 18:00 | Tenderness | Mild | 0 | | 16JUL2020 8:00 |
| | | 17JUL2020 20:00 | Pain | Mild | 1 | | 16JUL2020 8:00 |
| | | 17JUL2020 20:00 | Tenderness | Mild | 1 | | 16JUL2020 8:00 |
| | | 18JUL2020 20:00 | Tenderness | Mild | 2 | | 16JUL2020 8:00 |
| | | 19JUL2020 20:00 | Tenderness | Mild | 3 | | 16JUL2020 8:00 |
| | | 06AUG2020 22:00 | Pain | Mild | 21 | 0 | 16JUL2020 8:00 |
| | | 06AUG2020 22:00 | Tenderness | Mild | 21 | 0 | 16JUL2020 8:00 |
| | | 07AUG2020 22:00 | Pain | Mild | 22 | 1 | 16JUL2020 8:00 |
| | | 07AUG2020 22:00 | Tenderness | Mild | 22 | 1 | 16JUL2020 8:00 |
| | | 08AUG2020 22:00 | Pain | Mild | 23 | 2 | 16JUL2020 8:00 |
| | | 08AUG2020 22:00 | Tenderness | Mild | 23 | 2 | 16JUL2020 8:00 |
| | | 09AUG2020 22:00 | Pain | Mild | 24 | 3 | 16JUL2020 8:00 |
| | | 09AUG2020 22:00 | Tenderness | Mild | 24 | 3 | 16JUL2020 8:00 |
| | | 10AUG2020 22:00 | Pain | Mild | 25 | 4 | 16JUL2020 8:00 |
| | | 10AUG2020 22:00 | Tenderness | Mild | 25 | 4 | 16JUL2020 8:00 |
| 11AUG2020 22:00 | Pain | Mild | 26 | 5 | 16JUL2020 8:00 | | |
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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|---------------|--|-------------------------|-----------------|---------------------|---|---|---------------------------------|----------------|
| 20 µg Younger | 10151 | 11AUG2020 22:00 | Tenderness | Mild | 26 | 5 | 16JUL2020 8:00 | |
| | | 12AUG2020 22:00 | Tenderness | Mild | 27 | 6 | 16JUL2020 8:00 | |
| | 10171 | 16JUL2020 17:40 | Tenderness | Mild | 0 | | 16JUL2020 8:15 | |
| | | 17JUL2020 20:28 | Tenderness | Mild | 1 | | 16JUL2020 8:15 | |
| | | 18JUL2020 20:10 | Tenderness | Mild | 2 | | 16JUL2020 8:15 | |
| | | 19JUL2020 21:07 | Tenderness | Mild | 3 | | 16JUL2020 8:15 | |
| | | 06AUG2020 20:22 | Pain | Moderate | 21 | 0 | 16JUL2020 8:15 | |
| | | 06AUG2020 20:22 | Tenderness | Moderate | 21 | 0 | 16JUL2020 8:15 | |
| | | 07AUG2020 20:10 | Pain | Mild | 22 | 1 | 16JUL2020 8:15 | |
| | | 07AUG2020 20:10 | Tenderness | Mild | 22 | 1 | 16JUL2020 8:15 | |
| | | 08AUG2020 20:06 | Pain | Mild | 23 | 2 | 16JUL2020 8:15 | |
| | | 08AUG2020 20:06 | Tenderness | Mild | 23 | 2 | 16JUL2020 8:15 | |
| | | 09AUG2020 19:40 | Pain | Mild | 24 | 3 | 16JUL2020 8:15 | |
| | | 09AUG2020 19:40 | Tenderness | Mild | 24 | 3 | 16JUL2020 8:15 | |
| | | 10AUG2020 20:13 | Pain | Mild | 25 | 4 | 16JUL2020 8:15 | |
| | | 10AUG2020 20:13 | Tenderness | Mild | 25 | 4 | 16JUL2020 8:15 | |
| | | 10172 | 16JUL2020 20:15 | Pain | Moderate | 0 | | 16JUL2020 8:30 |
| | | | 16JUL2020 20:15 | Tenderness | Mild | 0 | | 16JUL2020 8:30 |
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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 10172 | 17JUL2020 20:22 | Pain | Mild | 1 | | 16JUL2020 8:30 |
| | | 17JUL2020 20:22 | Tenderness | Mild | 1 | | 16JUL2020 8:30 |
| | | 06AUG2020 19:50 | Pain | Moderate | 21 | 0 | 16JUL2020 8:30 |
| | | 06AUG2020 19:50 | Tenderness | Moderate | 21 | 0 | 16JUL2020 8:30 |
| | 10173 | 17JUL2020 16:00 | Pain | Mild | 1 | | 16JUL2020 8:45 |
| | | 17JUL2020 16:00 | Tenderness | Mild | 1 | | 16JUL2020 8:45 |
| | | 06AUG2020 22:00 | Pain | Mild | 21 | 0 | 16JUL2020 8:45 |
| | | 06AUG2020 22:00 | Tenderness | Moderate | 21 | 0 | 16JUL2020 8:45 |
| | | 08AUG2020 22:00 | Pain | Mild | 23 | 2 | 16JUL2020 8:45 |
| | | 08AUG2020 22:00 | Tenderness | Mild | 23 | 2 | 16JUL2020 8:45 |
| | | 09AUG2020 13:00 | Tenderness | Mild | 24 | 3 | 16JUL2020 8:45 |
| | 10175 | 17JUL2020 17:54 | Pain | Mild | 1 | | 16JUL2020 9:00 |
| | | 17JUL2020 17:54 | Tenderness | Mild | 1 | | 16JUL2020 9:00 |
| | | 06AUG2020 21:00 | Tenderness | Mild | 21 | 0 | 16JUL2020 9:00 |
| | | 07AUG2020 21:08 | Tenderness | Mild | 22 | 1 | 16JUL2020 9:00 |
| | | 08AUG2020 21:01 | Tenderness | Mild | 23 | 2 | 16JUL2020 9:00 |
| | 10176 | 16JUL2020 21:00 | Pain | Mild | 0 | | 16JUL2020 9:15 |
| | | 16JUL2020 21:00 | Tenderness | Mild | 0 | | 16JUL2020 9:15 |
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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 10176 | 17JUL2020 20:30 | Pain | Mild | 1 | | 16JUL2020 9:15 |
| | | 17JUL2020 20:30 | Tenderness | Mild | 1 | | 16JUL2020 9:15 |
| | | 17JUL2020 20:30 | Induration/Swelling | Mild | 1 | | 16JUL2020 9:15 |
| | | 06AUG2020 22:00 | Tenderness | Mild | 21 | 0 | 16JUL2020 9:15 |
| | | 07AUG2020 22:00 | Tenderness | Mild | 22 | 1 | 16JUL2020 9:15 |
| | | 08AUG2020 21:00 | Tenderness | Mild | 23 | 2 | 16JUL2020 9:15 |
| | | 08AUG2020 21:00 | Erythema/Redness | Mild | 23 | 2 | 16JUL2020 9:15 |
| | | 09AUG2020 22:00 | Erythema/Redness | Mild | 24 | 3 | 16JUL2020 9:15 |
| | 10178 | 16JUL2020 20:15 | Pain | Mild | 0 | | 16JUL2020 9:30 |
| | | 16JUL2020 20:15 | Tenderness | Mild | 0 | | 16JUL2020 9:30 |
| | | 17JUL2020 20:00 | Pain | Mild | 1 | | 16JUL2020 9:30 |
| | | 17JUL2020 20:00 | Tenderness | Mild | 1 | | 16JUL2020 9:30 |
| | | 18JUL2020 20:20 | Pain | Mild | 2 | | 16JUL2020 9:30 |
| | | 18JUL2020 20:20 | Tenderness | Mild | 2 | | 16JUL2020 9:30 |
| | | 19JUL2020 19:40 | Tenderness | Mild | 3 | | 16JUL2020 9:30 |
| | | 20JUL2020 20:00 | Tenderness | Mild | 4 | | 16JUL2020 9:30 |
| | | 06AUG2020 19:40 | Tenderness | Mild | 21 | 0 | 16JUL2020 9:30 |
| | | 07AUG2020 19:00 | Tenderness | Mild | 22 | 1 | 16JUL2020 9:30 |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|---------------|--|-------------------------|----------------|---------------------|---|---|---------------------------------|--|
| 20 µg Younger | 10178 | 08AUG2020 19:30 | Tenderness | Mild | 23 | 2 | 16JUL2020 9:30 | |
| | 10179 | 16JUL2020 21:00 | Pain | Mild | 0 | | 16JUL2020 9:45 | |
| | | 06AUG2020 21:00 | Pain | Mild | 21 | 0 | 16JUL2020 9:45 | |
| | | 06AUG2020 21:00 | Tenderness | Mild | 21 | 0 | 16JUL2020 9:45 | |
| | 10181 | 16JUL2020 20:15 | Pain | Moderate | 0 | | 16JUL2020 10:00 | |
| | | 16JUL2020 20:15 | Tenderness | Moderate | 0 | | 16JUL2020 10:00 | |
| | | 17JUL2020 20:45 | Pain | Moderate | 1 | | 16JUL2020 10:00 | |
| | | 17JUL2020 20:45 | Tenderness | Moderate | 1 | | 16JUL2020 10:00 | |
| | | 18JUL2020 20:45 | Pain | Mild | 2 | | 16JUL2020 10:00 | |
| | | 18JUL2020 20:45 | Tenderness | Mild | 2 | | 16JUL2020 10:00 | |
| | | 06AUG2020 20:30 | Pain | Mild | 21 | 0 | 16JUL2020 10:00 | |
| | | 06AUG2020 20:30 | Tenderness | Mild | 21 | 0 | 16JUL2020 10:00 | |
| | | 07AUG2020 21:10 | Pain | Mild | 22 | 1 | 16JUL2020 10:00 | |
| | | 07AUG2020 21:10 | Tenderness | Mild | 22 | 1 | 16JUL2020 10:00 | |
| | | 08AUG2020 20:40 | Pain | Mild | 23 | 2 | 16JUL2020 10:00 | |
| | | 08AUG2020 20:40 | Tenderness | Mild | 23 | 2 | 16JUL2020 10:00 | |
| | 10182 | 16JUL2020 19:31 | Pain | Mild | 0 | | 16JUL2020 10:15 | |
| | | 16JUL2020 19:31 | Tenderness | Mild | 0 | | 16JUL2020 10:15 | |
| | Program: Lsaf_locR_1.sas (Page 15 of 56) | | | | | | | |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-----------------|-----------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 10183 | 16JUL2020 20:30 | Pain | Severe | 0 | | 16JUL2020 10:30 |
| | | 16JUL2020 20:30 | Tenderness | Severe | 0 | | 16JUL2020 10:30 |
| | | 17JUL2020 0:00 | Pain | Moderate | 1 | | 16JUL2020 10:30 |
| | | 17JUL2020 0:00 | Tenderness | Moderate | 1 | | 16JUL2020 10:30 |
| | | 18JUL2020 7:15 | Pain | Mild | 2 | | 16JUL2020 10:30 |
| | | 18JUL2020 7:15 | Tenderness | Mild | 2 | | 16JUL2020 10:30 |
| | | 06AUG2020 18:30 | Pain | Mild | 21 | 0 | 16JUL2020 10:30 |
| | | 06AUG2020 18:30 | Tenderness | Mild | 21 | 0 | 16JUL2020 10:30 |
| | | 06AUG2020 18:30 | Induration/Swelling | Mild | 21 | 0 | 16JUL2020 10:30 |
| | | 07AUG2020 20:10 | Pain | Mild | 22 | 1 | 16JUL2020 10:30 |
| | | 07AUG2020 20:10 | Tenderness | Mild | 22 | 1 | 16JUL2020 10:30 |
| | | 07AUG2020 20:10 | Induration/Swelling | Mild | 22 | 1 | 16JUL2020 10:30 |
| | | 08AUG2020 20:45 | Pain | Mild | 23 | 2 | 16JUL2020 10:30 |
| | | 08AUG2020 20:45 | Tenderness | Mild | 23 | 2 | 16JUL2020 10:30 |
| | 09AUG2020 21:00 | Tenderness | Mild | 24 | 3 | 16JUL2020 10:30 | |
| | 10197 | 16JUL2020 20:30 | Pain | Moderate | 0 | | 16JUL2020 10:45 |
| | | 16JUL2020 20:30 | Tenderness | Moderate | 0 | | 16JUL2020 10:45 |
| 17JUL2020 20:30 | | Pain | Severe | 1 | | 16JUL2020 10:45 | |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 10197 | 17JUL2020 20:30 | Tenderness | Moderate | 1 | | 16JUL2020 10:45 |
| | | 18JUL2020 18:30 | Pain | Mild | 2 | | 16JUL2020 10:45 |
| | | 18JUL2020 18:30 | Tenderness | Moderate | 2 | | 16JUL2020 10:45 |
| | | 19JUL2020 18:20 | Pain | Mild | 3 | | 16JUL2020 10:45 |
| | | 19JUL2020 18:20 | Tenderness | Mild | 3 | | 16JUL2020 10:45 |
| | | 20JUL2020 18:00 | Tenderness | Mild | 4 | | 16JUL2020 10:45 |
| | | 06AUG2020 22:00 | Pain | Mild | 21 | 0 | 16JUL2020 10:45 |
| | | 06AUG2020 22:00 | Tenderness | Mild | 21 | 0 | 16JUL2020 10:45 |
| | | 07AUG2020 18:30 | Pain | Moderate | 22 | 1 | 16JUL2020 10:45 |
| | | 07AUG2020 18:30 | Tenderness | Mild | 22 | 1 | 16JUL2020 10:45 |
| | | 08AUG2020 18:30 | Pain | Mild | 23 | 2 | 16JUL2020 10:45 |
| | | 08AUG2020 18:30 | Tenderness | Mild | 23 | 2 | 16JUL2020 10:45 |
| | | 09AUG2020 18:00 | Pain | Mild | 24 | 3 | 16JUL2020 10:45 |
| | | 09AUG2020 18:00 | Tenderness | Mild | 24 | 3 | 16JUL2020 10:45 |
| 10AUG2020 17:15 | Tenderness | Mild | 25 | 4 | 16JUL2020 10:45 | | |
| 30 µg Younger | 10016 | 29APR2020 | Pain | Severe | 0 | | 29APR2020 9:03 |
| | | 29APR2020 | Tenderness | Severe | 0 | | 29APR2020 9:03 |
| | | 30APR2020 | Pain | Mild | 1 | | 29APR2020 9:03 |
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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 10016 | 30APR2020 | Tenderness | Mild | 1 | | 29APR2020 9:03 |
| | | 20MAY2020 | Pain | Mild | 21 | 0 | 29APR2020 9:03 |
| | | 20MAY2020 | Tenderness | Mild | 21 | 0 | 29APR2020 9:03 |
| | | 21MAY2020 | Pain | Moderate | 22 | 1 | 29APR2020 9:03 |
| | | 21MAY2020 | Tenderness | Moderate | 22 | 1 | 29APR2020 9:03 |
| | | 24MAY2020 | Tenderness | Mild | 25 | 4 | 29APR2020 9:03 |
| | 10020 | 20MAY2020 19:00 | Pain | Mild | 21 | 0 | 29APR2020 10:06 |
| | 10021 | 05MAY2020 20:00 | Pain | Mild | 0 | | 05MAY2020 8:30 |
| | | 05MAY2020 20:00 | Tenderness | Mild | 0 | | 05MAY2020 8:30 |
| | | 06MAY2020 20:00 | Pain | Mild | 1 | | 05MAY2020 8:30 |
| | | 06MAY2020 20:00 | Tenderness | Mild | 1 | | 05MAY2020 8:30 |
| | | 10MAY2020 20:01 | Tenderness | Mild | 5 | | 05MAY2020 8:30 |
| | | 26MAY2020 20:00 | Pain | Severe | 21 | 0 | 05MAY2020 8:30 |
| | | 26MAY2020 20:00 | Tenderness | Severe | 21 | 0 | 05MAY2020 8:30 |
| | | 27MAY2020 20:00 | Pain | Moderate | 22 | 1 | 05MAY2020 8:30 |
| | | 27MAY2020 20:00 | Tenderness | Moderate | 22 | 1 | 05MAY2020 8:30 |
| | | 28MAY2020 20:00 | Pain | Moderate | 23 | 2 | 05MAY2020 8:30 |
| | | 28MAY2020 20:00 | Tenderness | Moderate | 23 | 2 | 05MAY2020 8:30 |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 10028 | 07MAY2020 21:27 | Pain | Mild | 0 | | 07MAY2020 8:30 |
| | | 07MAY2020 21:27 | Tenderness | Mild | 0 | | 07MAY2020 8:30 |
| | | 08MAY2020 21:40 | Pain | Mild | 1 | | 07MAY2020 8:30 |
| | | 08MAY2020 21:40 | Tenderness | Mild | 1 | | 07MAY2020 8:30 |
| | | 09MAY2020 22:00 | Pain | Mild | 2 | | 07MAY2020 8:30 |
| | | 09MAY2020 22:00 | Tenderness | Mild | 2 | | 07MAY2020 8:30 |
| | | 09MAY2020 22:00 | Erythema/Redness | Mild | 2 | | 07MAY2020 8:30 |
| | | 10MAY2020 22:00 | Pain | Mild | 3 | | 07MAY2020 8:30 |
| | | 10MAY2020 22:00 | Tenderness | Mild | 3 | | 07MAY2020 8:30 |
| | | 10MAY2020 22:00 | Erythema/Redness | Mild | 3 | | 07MAY2020 8:30 |
| | | 28MAY2020 22:00 | Pain | Mild | 21 | 0 | 07MAY2020 8:30 |
| | | 28MAY2020 22:00 | Tenderness | Mild | 21 | 0 | 07MAY2020 8:30 |
| | | 29MAY2020 22:00 | Pain | Moderate | 22 | 1 | 07MAY2020 8:30 |
| | | 29MAY2020 22:00 | Tenderness | Moderate | 22 | 1 | 07MAY2020 8:30 |
| | 10031 | 07MAY2020 22:00 | Pain | Severe | 0 | | 07MAY2020 9:00 |
| | | 07MAY2020 22:00 | Tenderness | Severe | 0 | | 07MAY2020 9:00 |
| | | 08MAY2020 22:00 | Pain | Mild | 1 | | 07MAY2020 9:00 |
| | | 08MAY2020 22:00 | Tenderness | Mild | 1 | | 07MAY2020 9:00 |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 10031 | 09MAY2020 22:00 | Tenderness | Mild | 2 | | 07MAY2020 9:00 |
| | | 28MAY2020 22:00 | Pain | Moderate | 21 | 0 | 07MAY2020 9:00 |
| | | 28MAY2020 22:00 | Tenderness | Moderate | 21 | 0 | 07MAY2020 9:00 |
| | | 29MAY2020 22:00 | Pain | Mild | 22 | 1 | 07MAY2020 9:00 |
| | | 29MAY2020 22:00 | Tenderness | Moderate | 22 | 1 | 07MAY2020 9:00 |
| | | 30MAY2020 22:00 | Pain | Mild | 23 | 2 | 07MAY2020 9:00 |
| | | 30MAY2020 22:00 | Tenderness | Mild | 23 | 2 | 07MAY2020 9:00 |
| | | 31MAY2020 22:00 | Pain | Mild | 24 | 3 | 07MAY2020 9:00 |
| | | 31MAY2020 22:00 | Tenderness | Mild | 24 | 3 | 07MAY2020 9:00 |
| | | 01JUN2020 22:00 | Tenderness | Mild | 25 | 4 | 07MAY2020 9:00 |
| | | 03JUN2020 22:00 | Tenderness | Mild | 27 | 6 | 07MAY2020 9:00 |
| | 10032 | 05MAY2020 19:00 | Tenderness | Mild | 0 | | 05MAY2020 9:00 |
| | | 06MAY2020 18:33 | Tenderness | Mild | 1 | | 05MAY2020 9:00 |
| | | 26MAY2020 19:20 | Pain | Mild | 21 | 0 | 05MAY2020 9:00 |
| | | 26MAY2020 19:20 | Tenderness | Mild | 21 | 0 | 05MAY2020 9:00 |
| | | 27MAY2020 18:35 | Pain | Mild | 22 | 1 | 05MAY2020 9:00 |
| | | 27MAY2020 18:35 | Tenderness | Moderate | 22 | 1 | 05MAY2020 9:00 |
| | 10034 | 05MAY2020 22:05 | Pain | Mild | 0 | | 05MAY2020 9:30 |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|------------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 10034 | 05MAY2020 22:05 | Tenderness | Mild | 0 | | 05MAY2020 9:30 |
| | | 05MAY2020 22:05 | Induration/Swelling | Mild | 0 | | 05MAY2020 9:30 |
| | | 06MAY2020 20:10 | Tenderness | Moderate | 1 | | 05MAY2020 9:30 |
| | | 06MAY2020 20:10 | Erythema/Redness | Mild | 1 | | 05MAY2020 9:30 |
| | | 07MAY2020 20:10 | Pain | Mild | 2 | | 05MAY2020 9:30 |
| | | 07MAY2020 20:10 | Tenderness | Mild | 2 | | 05MAY2020 9:30 |
| | | 07MAY2020 20:10 | Erythema/Redness | Mild | 2 | | 05MAY2020 9:30 |
| | | 08MAY2020 12:15 | Pain | Mild | 3 | | 05MAY2020 9:30 |
| | | 08MAY2020 12:15 | Tenderness | Mild | 3 | | 05MAY2020 9:30 |
| | | 08MAY2020 12:15 | Erythema/Redness | Mild | 3 | | 05MAY2020 9:30 |
| | | 08MAY2020 12:15 | Induration/Swelling | Mild | 3 | | 05MAY2020 9:30 |
| | | 09MAY2020 20:00 | Pain | Mild | 4 | | 05MAY2020 9:30 |
| | | 09MAY2020 20:00 | Tenderness | Moderate | 4 | | 05MAY2020 9:30 |
| | | 09MAY2020 20:00 | Erythema/Redness | Mild | 4 | | 05MAY2020 9:30 |
| | | 09MAY2020 20:00 | Induration/Swelling | Mild | 4 | | 05MAY2020 9:30 |
| | | 10MAY2020 20:00 | Pain | Mild | 5 | | 05MAY2020 9:30 |
| | | 10MAY2020 20:00 | Tenderness | Moderate | 5 | | 05MAY2020 9:30 |
| 10MAY2020 20:00 | Erythema/Redness | Mild | 5 | | 05MAY2020 9:30 | | |
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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 10034 | 10MAY2020 20:00 | Induration/Swelling | Mild | 5 | | 05MAY2020 9:30 |
| | | 11MAY2020 20:10 | Erythema/Redness | Mild | 6 | | 05MAY2020 9:30 |
| | | 11MAY2020 20:10 | Induration/Swelling | Mild | 6 | | 05MAY2020 9:30 |
| | | 26MAY2020 23:00 | Pain | Moderate | 21 | 0 | 05MAY2020 9:30 |
| | | 26MAY2020 23:00 | Tenderness | Moderate | 21 | 0 | 05MAY2020 9:30 |
| | | 27MAY2020 21:00 | Pain | Mild | 22 | 1 | 05MAY2020 9:30 |
| | | 27MAY2020 21:00 | Tenderness | Moderate | 22 | 1 | 05MAY2020 9:30 |
| | | 28MAY2020 21:00 | Tenderness | Mild | 23 | 2 | 05MAY2020 9:30 |
| | 10037 | 05MAY2020 21:00 | Tenderness | Mild | 0 | | 05MAY2020 10:00 |
| | | 06MAY2020 21:00 | Tenderness | Mild | 1 | | 05MAY2020 10:00 |
| | | 07MAY2020 21:00 | Pain | Mild | 2 | | 05MAY2020 10:00 |
| | | 07MAY2020 21:00 | Tenderness | Mild | 2 | | 05MAY2020 10:00 |
| | | 26MAY2020 21:00 | Pain | Moderate | 21 | 0 | 05MAY2020 10:00 |
| | | 26MAY2020 21:00 | Tenderness | Moderate | 21 | 0 | 05MAY2020 10:00 |
| | | 27MAY2020 21:00 | Pain | Moderate | 22 | 1 | 05MAY2020 10:00 |
| | | 27MAY2020 21:00 | Tenderness | Moderate | 22 | 1 | 05MAY2020 10:00 |
| | | 28MAY2020 21:00 | Pain | Mild | 23 | 2 | 05MAY2020 10:00 |
| | | 28MAY2020 21:00 | Tenderness | Moderate | 23 | 2 | 05MAY2020 10:00 |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|---------------|--|-------------------------|----------------|---------------------|---|---|---------------------------------|--|
| 30 µg Younger | 10037 | 29MAY2020 21:00 | Pain | Mild | 24 | 3 | 05MAY2020 10:00 | |
| | | 29MAY2020 21:00 | Tenderness | Mild | 24 | 3 | 05MAY2020 10:00 | |
| | 10038 | 07MAY2020 21:00 | Pain | Mild | 0 | | 07MAY2020 9:30 | |
| | | 07MAY2020 21:00 | Tenderness | Moderate | 0 | | 07MAY2020 9:30 | |
| | 10039 | 07MAY2020 22:00 | Pain | Severe | 0 | | 07MAY2020 10:00 | |
| | | 07MAY2020 22:00 | Tenderness | Moderate | 0 | | 07MAY2020 10:00 | |
| | | 08MAY2020 22:00 | Pain | Severe | 1 | | 07MAY2020 10:00 | |
| | | 08MAY2020 22:00 | Tenderness | Moderate | 1 | | 07MAY2020 10:00 | |
| | | 09MAY2020 22:00 | Pain | Mild | 2 | | 07MAY2020 10:00 | |
| | | 09MAY2020 22:00 | Tenderness | Mild | 2 | | 07MAY2020 10:00 | |
| | | 28MAY2020 22:00 | Pain | Severe | 21 | 0 | 07MAY2020 10:00 | |
| | | 28MAY2020 22:00 | Tenderness | Moderate | 21 | 0 | 07MAY2020 10:00 | |
| | | 29MAY2020 22:00 | Pain | Moderate | 22 | 1 | 07MAY2020 10:00 | |
| | | 29MAY2020 22:00 | Tenderness | Mild | 22 | 1 | 07MAY2020 10:00 | |
| | 30MAY2020 22:00 | Tenderness | Mild | 23 | 2 | 07MAY2020 10:00 | | |
| | 10043 | 07MAY2020 20:00 | Pain | Mild | 0 | | 07MAY2020 10:30 | |
| | | 07MAY2020 20:00 | Tenderness | Moderate | 0 | | 07MAY2020 10:30 | |
| | | 08MAY2020 20:00 | Pain | Mild | 1 | | 07MAY2020 10:30 | |
| | Program: Lsaf_locR_1.sas (Page 23 of 56) | | | | | | | |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 10043 | 08MAY2020 20:00 | Tenderness | Severe | 1 | | 07MAY2020 10:30 |
| | | 08MAY2020 20:00 | Erythema/Redness | Mild | 1 | | 07MAY2020 10:30 |
| | | 08MAY2020 20:00 | Induration/Swelling | Mild | 1 | | 07MAY2020 10:30 |
| | | 09MAY2020 20:00 | Pain | Mild | 2 | | 07MAY2020 10:30 |
| | | 09MAY2020 20:00 | Tenderness | Moderate | 2 | | 07MAY2020 10:30 |
| | | 09MAY2020 20:00 | Erythema/Redness | Mild | 2 | | 07MAY2020 10:30 |
| | | 09MAY2020 20:00 | Induration/Swelling | Mild | 2 | | 07MAY2020 10:30 |
| | | 10MAY2020 20:00 | Pain | Mild | 3 | | 07MAY2020 10:30 |
| | | 10MAY2020 20:00 | Tenderness | Mild | 3 | | 07MAY2020 10:30 |
| | | 10MAY2020 20:00 | Erythema/Redness | Mild | 3 | | 07MAY2020 10:30 |
| | | 10MAY2020 20:00 | Induration/Swelling | Mild | 3 | | 07MAY2020 10:30 |
| | | 11MAY2020 20:00 | Pain | Mild | 4 | | 07MAY2020 10:30 |
| | | 11MAY2020 20:00 | Tenderness | Mild | 4 | | 07MAY2020 10:30 |
| | | 11MAY2020 20:00 | Erythema/Redness | Mild | 4 | | 07MAY2020 10:30 |
| | | 11MAY2020 20:00 | Induration/Swelling | Mild | 4 | | 07MAY2020 10:30 |
| | | 12MAY2020 20:00 | Pain | Mild | 5 | | 07MAY2020 10:30 |
| | | 12MAY2020 20:00 | Tenderness | Mild | 5 | | 07MAY2020 10:30 |
| | | 12MAY2020 20:00 | Erythema/Redness | Mild | 5 | | 07MAY2020 10:30 |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|--|---------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 10043 | 12MAY2020 20:00 | Induration/Swelling | Mild | 5 | | 07MAY2020 10:30 |
| | | 28MAY2020 20:00 | Pain | Mild | 21 | 0 | 07MAY2020 10:30 |
| | | 28MAY2020 20:00 | Tenderness | Mild | 21 | 0 | 07MAY2020 10:30 |
| | | 29MAY2020 20:00 | Pain | Moderate | 22 | 1 | 07MAY2020 10:30 |
| | | 29MAY2020 20:00 | Tenderness | Moderate | 22 | 1 | 07MAY2020 10:30 |
| | | 30MAY2020 20:00 | Pain | Mild | 23 | 2 | 07MAY2020 10:30 |
| | | 31MAY2020 20:00 | Pain | Mild | 24 | 3 | 07MAY2020 10:30 |
| | 10047 | 07MAY2020 23:00 | Pain | Mild | 0 | | 07MAY2020 11:00 |
| | | 07MAY2020 23:00 | Tenderness | Moderate | 0 | | 07MAY2020 11:00 |
| | | 08MAY2020 23:45 | Pain | Mild | 1 | | 07MAY2020 11:00 |
| | | 08MAY2020 23:45 | Tenderness | Mild | 1 | | 07MAY2020 11:00 |
| | | 09MAY2020 23:45 | Tenderness | Mild | 2 | | 07MAY2020 11:00 |
| | | 10MAY2020 23:40 | Tenderness | Mild | 3 | | 07MAY2020 11:00 |
| | | 28MAY2020 23:55 | Pain | Mild | 21 | 0 | 07MAY2020 11:00 |
| | | 28MAY2020 23:55 | Tenderness | Moderate | 21 | 0 | 07MAY2020 11:00 |
| | | 29MAY2020 21:00 | Pain | Moderate | 22 | 1 | 07MAY2020 11:00 |
| | | 29MAY2020 21:00 | Tenderness | Moderate | 22 | 1 | 07MAY2020 11:00 |
| | | 30MAY2020 23:55 | Pain | Mild | 23 | 2 | 07MAY2020 11:00 |
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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-----------------|----------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 10047 | 30MAY2020 23:55 | Tenderness | Mild | 23 | 2 | 07MAY2020 11:00 |
| | | 31MAY2020 22:00 | Tenderness | Mild | 24 | 3 | 07MAY2020 11:00 |
| 50 µg Younger | 10049 | 12MAY2020 19:30 | Pain | Mild | 0 | | 12MAY2020 9:10 |
| | | 12MAY2020 19:30 | Tenderness | Moderate | 0 | | 12MAY2020 9:10 |
| | | 13MAY2020 13:00 | Pain | Mild | 1 | | 12MAY2020 9:10 |
| | | 13MAY2020 13:00 | Tenderness | Mild | 1 | | 12MAY2020 9:10 |
| | | 02JUN2020 23:00 | Pain | Mild | 21 | 0 | 12MAY2020 9:10 |
| | | 02JUN2020 23:00 | Tenderness | Mild | 21 | 0 | 12MAY2020 9:10 |
| | | 02JUN2020 23:00 | Induration/Swelling | Mild | 21 | 0 | 12MAY2020 9:10 |
| | | 03JUN2020 7:15 | Pain | Mild | 22 | 1 | 12MAY2020 9:10 |
| | | 03JUN2020 7:15 | Tenderness | Mild | 22 | 1 | 12MAY2020 9:10 |
| | | 03JUN2020 7:15 | Induration/Swelling | Mild | 22 | 1 | 12MAY2020 9:10 |
| | 10050 | 15MAY2020 19:15 | Pain | Moderate | 0 | | 15MAY2020 8:45 |
| | | 15MAY2020 19:15 | Tenderness | Moderate | 0 | | 15MAY2020 8:45 |
| | | 15MAY2020 19:15 | Erythema/Redness | Mild | 0 | | 15MAY2020 8:45 |
| | | 15MAY2020 19:15 | Induration/Swelling | Mild | 0 | | 15MAY2020 8:45 |
| 16MAY2020 19:43 | | Pain | Moderate | 1 | | 15MAY2020 8:45 | |
| 16MAY2020 19:43 | | Tenderness | Moderate | 1 | | 15MAY2020 8:45 | |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|-----------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10050 | 17MAY2020 20:17 | Pain | Mild | 2 | | 15MAY2020 8:45 |
| | | 17MAY2020 20:17 | Tenderness | Moderate | 2 | | 15MAY2020 8:45 |
| | | 17MAY2020 20:17 | Erythema/Redness | Moderate | 2 | | 15MAY2020 8:45 |
| | | 17MAY2020 20:17 | Induration/Swelling | Mild | 2 | | 15MAY2020 8:45 |
| | | 18MAY2020 20:00 | Pain | Mild | 3 | | 15MAY2020 8:45 |
| | | 18MAY2020 20:00 | Tenderness | Mild | 3 | | 15MAY2020 8:45 |
| | | 18MAY2020 20:00 | Erythema/Redness | Mild | 3 | | 15MAY2020 8:45 |
| | | 18MAY2020 20:00 | Induration/Swelling | Mild | 3 | | 15MAY2020 8:45 |
| | | 19MAY2020 21:20 | Pain | Mild | 4 | | 15MAY2020 8:45 |
| | | 19MAY2020 21:20 | Tenderness | Mild | 4 | | 15MAY2020 8:45 |
| | | 19MAY2020 21:20 | Erythema/Redness | Mild | 4 | | 15MAY2020 8:45 |
| | | 20MAY2020 19:25 | Pain | Mild | 5 | | 15MAY2020 8:45 |
| | | 20MAY2020 19:25 | Tenderness | Mild | 5 | | 15MAY2020 8:45 |
| | | 21MAY2020 20:13 | Pain | Mild | 6 | | 15MAY2020 8:45 |
| | | 21MAY2020 20:13 | Tenderness | Mild | 6 | | 15MAY2020 8:45 |
| | | | 10053 | 12MAY2020 20:00 | Pain | Mild | 0 |
| | 12MAY2020 20:00 | Tenderness | | Mild | 0 | | 12MAY2020 10:13 |
| | 13MAY2020 20:00 | Pain | | Mild | 1 | | 12MAY2020 10:13 |
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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|---------------|--|-------------------------|----------------|---------------------|---|---|---------------------------------|--|
| 50 µg Younger | 10053 | 13MAY2020 20:00 | Tenderness | Moderate | 1 | | 12MAY2020 10:13 | |
| | | 14MAY2020 20:00 | Tenderness | Mild | 2 | | 12MAY2020 10:13 | |
| | | 15MAY2020 20:00 | Tenderness | Mild | 3 | | 12MAY2020 10:13 | |
| | | 02JUN2020 20:00 | Pain | Mild | 21 | 0 | 12MAY2020 10:13 | |
| | | 02JUN2020 20:00 | Tenderness | Mild | 21 | 0 | 12MAY2020 10:13 | |
| | | 03JUN2020 20:00 | Pain | Mild | 22 | 1 | 12MAY2020 10:13 | |
| | | 03JUN2020 20:00 | Tenderness | Mild | 22 | 1 | 12MAY2020 10:13 | |
| | 10055 | 14MAY2020 21:30 | Pain | Mild | 1 | | 13MAY2020 9:13 | |
| | | 14MAY2020 21:30 | Tenderness | Mild | 1 | | 13MAY2020 9:13 | |
| | | 15MAY2020 22:00 | Pain | Mild | 2 | | 13MAY2020 9:13 | |
| | | 15MAY2020 22:00 | Tenderness | Mild | 2 | | 13MAY2020 9:13 | |
| | | 03JUN2020 8:30 | Pain | Mild | 21 | 0 | 13MAY2020 9:13 | |
| | | 03JUN2020 8:30 | Tenderness | Mild | 21 | 0 | 13MAY2020 9:13 | |
| | | 04JUN2020 22:48 | Tenderness | Mild | 22 | 1 | 13MAY2020 9:13 | |
| | 10056 | 13MAY2020 20:30 | Pain | Mild | 0 | | 13MAY2020 10:16 | |
| | | 13MAY2020 20:30 | Tenderness | Mild | 0 | | 13MAY2020 10:16 | |
| | | 14MAY2020 20:30 | Pain | Mild | 1 | | 13MAY2020 10:16 | |
| | | 14MAY2020 20:30 | Tenderness | Mild | 1 | | 13MAY2020 10:16 | |
| | Program: Lsaf_locR_1.sas (Page 28 of 56) | | | | | | | |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|--|----------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10056 | 03JUN2020 21:30 | Pain | Mild | 21 | 0 | 13MAY2020 10:16 |
| | | 03JUN2020 21:30 | Tenderness | Mild | 21 | 0 | 13MAY2020 10:16 |
| | | 04JUN2020 21:30 | Pain | Moderate | 22 | 1 | 13MAY2020 10:16 |
| | | 04JUN2020 21:30 | Tenderness | Moderate | 22 | 1 | 13MAY2020 10:16 |
| | | 05JUN2020 21:30 | Pain | Mild | 23 | 2 | 13MAY2020 10:16 |
| | | 05JUN2020 21:30 | Tenderness | Mild | 23 | 2 | 13MAY2020 10:16 |
| | | 06JUN2020 21:30 | Pain | Mild | 24 | 3 | 13MAY2020 10:16 |
| | | 06JUN2020 21:30 | Tenderness | Mild | 24 | 3 | 13MAY2020 10:16 |
| | 10057 | 15MAY2020 20:00 | Pain | Mild | 0 | | 15MAY2020 9:15 |
| | | 16MAY2020 20:00 | Pain | Moderate | 1 | | 15MAY2020 9:15 |
| | | 16MAY2020 20:00 | Tenderness | Moderate | 1 | | 15MAY2020 9:15 |
| | | 05JUN2020 20:38 | Pain | Moderate | 21 | 0 | 15MAY2020 9:15 |
| | | 05JUN2020 20:38 | Tenderness | Severe | 21 | 0 | 15MAY2020 9:15 |
| | | 06JUN2020 17:30 | Pain | Mild | 22 | 1 | 15MAY2020 9:15 |
| | | 06JUN2020 17:30 | Tenderness | Mild | 22 | 1 | 15MAY2020 9:15 |
| | | 07JUN2020 14:00 | Pain | Mild | 23 | 2 | 15MAY2020 9:15 |
| | | 07JUN2020 14:00 | Tenderness | Mild | 23 | 2 | 15MAY2020 9:15 |
| | | 08JUN2020 14:00 | Pain | Mild | 24 | 3 | 15MAY2020 9:15 |
| | | Program: Lsaf_locR_1.sas (Page 29 of 56) | | | | | |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10057 | 08JUN2020 14:00 | Tenderness | Mild | 24 | 3 | 15MAY2020 9:15 |
| | 10059 | 13MAY2020 16:50 | Pain | Mild | 0 | | 13MAY2020 10:46 |
| | | 13MAY2020 16:50 | Tenderness | Moderate | 0 | | 13MAY2020 10:46 |
| | | 14MAY2020 17:00 | Pain | Moderate | 1 | | 13MAY2020 10:46 |
| | | 14MAY2020 17:00 | Tenderness | Moderate | 1 | | 13MAY2020 10:46 |
| | | 15MAY2020 17:50 | Pain | Moderate | 2 | | 13MAY2020 10:46 |
| | | 15MAY2020 17:50 | Tenderness | Moderate | 2 | | 13MAY2020 10:46 |
| | | 16MAY2020 17:30 | Pain | Moderate | 3 | | 13MAY2020 10:46 |
| | | 16MAY2020 17:30 | Tenderness | Moderate | 3 | | 13MAY2020 10:46 |
| | | 17MAY2020 17:15 | Pain | Moderate | 4 | | 13MAY2020 10:46 |
| | | 17MAY2020 17:15 | Tenderness | Moderate | 4 | | 13MAY2020 10:46 |
| | | 03JUN2020 11:50 | Pain | Moderate | 21 | 0 | 13MAY2020 10:46 |
| | | 03JUN2020 11:50 | Tenderness | Moderate | 21 | 0 | 13MAY2020 10:46 |
| | | 04JUN2020 10:00 | Pain | Moderate | 22 | 1 | 13MAY2020 10:46 |
| | | 04JUN2020 10:00 | Tenderness | Moderate | 22 | 1 | 13MAY2020 10:46 |
| | | 05JUN2020 18:00 | Pain | Moderate | 23 | 2 | 13MAY2020 10:46 |
| | | 05JUN2020 18:00 | Tenderness | Moderate | 23 | 2 | 13MAY2020 10:46 |
| | | 06JUN2020 17:00 | Pain | Moderate | 24 | 3 | 13MAY2020 10:46 |
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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|---------------|--|-------------------------|----------------|---------------------|---|---|---------------------------------|--|
| 50 µg Younger | 10059 | 06JUN2020 17:00 | Tenderness | Moderate | 24 | 3 | 13MAY2020 10:46 | |
| | | 07JUN2020 20:00 | Pain | Moderate | 25 | 4 | 13MAY2020 10:46 | |
| | | 07JUN2020 20:00 | Tenderness | Moderate | 25 | 4 | 13MAY2020 10:46 | |
| | | 08JUN2020 14:20 | Pain | Mild | 26 | 5 | 13MAY2020 10:46 | |
| | | 08JUN2020 14:20 | Tenderness | Mild | 26 | 5 | 13MAY2020 10:46 | |
| | 10060 | 14MAY2020 18:00 | Pain | Severe | 1 | | 13MAY2020 11:16 | |
| | | 14MAY2020 18:00 | Tenderness | Mild | 1 | | 13MAY2020 11:16 | |
| | | 04JUN2020 6:00 | Pain | Mild | 22 | 1 | 13MAY2020 11:16 | |
| | | 04JUN2020 6:00 | Tenderness | Mild | 22 | 1 | 13MAY2020 11:16 | |
| | 10067 | 15MAY2020 22:00 | Tenderness | Mild | 0 | | 15MAY2020 9:45 | |
| | | 05JUN2020 22:00 | Pain | Mild | 21 | 0 | 15MAY2020 9:45 | |
| | | 05JUN2020 22:00 | Tenderness | Mild | 21 | 0 | 15MAY2020 9:45 | |
| | | 06JUN2020 22:00 | Pain | Moderate | 22 | 1 | 15MAY2020 9:45 | |
| | | 06JUN2020 22:00 | Tenderness | Moderate | 22 | 1 | 15MAY2020 9:45 | |
| | 10068 | 15MAY2020 22:30 | Pain | Mild | 0 | | 15MAY2020 10:15 | |
| | | 15MAY2020 22:30 | Tenderness | Moderate | 0 | | 15MAY2020 10:15 | |
| | | 16MAY2020 23:00 | Pain | Mild | 1 | | 15MAY2020 10:15 | |
| | | 16MAY2020 23:00 | Tenderness | Moderate | 1 | | 15MAY2020 10:15 | |
| | Program: Lsaf_locR_1.sas (Page 31 of 56) | | | | | | | |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10068 | 16MAY2020 23:00 | Erythema/Redness | Mild | 1 | | 15MAY2020 10:15 |
| | | 16MAY2020 23:00 | Induration/Swelling | Mild | 1 | | 15MAY2020 10:15 |
| | | 17MAY2020 22:30 | Pain | Mild | 2 | | 15MAY2020 10:15 |
| | | 17MAY2020 22:30 | Tenderness | Mild | 2 | | 15MAY2020 10:15 |
| | | 17MAY2020 22:30 | Erythema/Redness | Moderate | 2 | | 15MAY2020 10:15 |
| | | 17MAY2020 22:30 | Induration/Swelling | Mild | 2 | | 15MAY2020 10:15 |
| | | 18MAY2020 23:00 | Pain | Mild | 3 | | 15MAY2020 10:15 |
| | | 18MAY2020 23:00 | Tenderness | Mild | 3 | | 15MAY2020 10:15 |
| | | 18MAY2020 23:00 | Erythema/Redness | Moderate | 3 | | 15MAY2020 10:15 |
| | | 18MAY2020 23:00 | Induration/Swelling | Mild | 3 | | 15MAY2020 10:15 |
| | | 19MAY2020 23:00 | Pain | Mild | 4 | | 15MAY2020 10:15 |
| | | 19MAY2020 23:00 | Tenderness | Mild | 4 | | 15MAY2020 10:15 |
| | | 19MAY2020 23:00 | Erythema/Redness | Moderate | 4 | | 15MAY2020 10:15 |
| | | 19MAY2020 23:00 | Induration/Swelling | Mild | 4 | | 15MAY2020 10:15 |
| | | 20MAY2020 23:30 | Pain | Mild | 5 | | 15MAY2020 10:15 |
| | | 20MAY2020 23:30 | Tenderness | Mild | 5 | | 15MAY2020 10:15 |
| | | 20MAY2020 23:30 | Erythema/Redness | Mild | 5 | | 15MAY2020 10:15 |
| | | | | 05JUN2020 22:30 | Pain | Moderate | 21 |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|------------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10068 | 05JUN2020 22:30 | Tenderness | Moderate | 21 | 0 | 15MAY2020 10:15 |
| | | 06JUN2020 22:00 | Pain | Moderate | 22 | 1 | 15MAY2020 10:15 |
| | | 06JUN2020 22:00 | Tenderness | Moderate | 22 | 1 | 15MAY2020 10:15 |
| | | 07JUN2020 22:30 | Pain | Mild | 23 | 2 | 15MAY2020 10:15 |
| | | 07JUN2020 22:30 | Tenderness | Moderate | 23 | 2 | 15MAY2020 10:15 |
| | | 07JUN2020 22:30 | Erythema/Redness | Mild | 23 | 2 | 15MAY2020 10:15 |
| | | 08JUN2020 23:00 | Pain | Mild | 24 | 3 | 15MAY2020 10:15 |
| | | 08JUN2020 23:00 | Tenderness | Moderate | 24 | 3 | 15MAY2020 10:15 |
| | | 08JUN2020 23:00 | Erythema/Redness | Mild | 24 | 3 | 15MAY2020 10:15 |
| | | 09JUN2020 23:00 | Pain | Mild | 25 | 4 | 15MAY2020 10:15 |
| | | 09JUN2020 23:00 | Tenderness | Mild | 25 | 4 | 15MAY2020 10:15 |
| | | 09JUN2020 23:00 | Erythema/Redness | Mild | 25 | 4 | 15MAY2020 10:15 |
| | | 10JUN2020 23:30 | Pain | Mild | 26 | 5 | 15MAY2020 10:15 |
| | | 10JUN2020 23:30 | Tenderness | Mild | 26 | 5 | 15MAY2020 10:15 |
| | | 11JUN2020 23:00 | Pain | Mild | 27 | 6 | 15MAY2020 10:15 |
| | | 11JUN2020 23:00 | Tenderness | Mild | 27 | 6 | 15MAY2020 10:15 |
| | 10070 | 16MAY2020 19:00 | Pain | Severe | 1 | | 15MAY2020 10:45 |
| | | 16MAY2020 19:00 | Tenderness | Severe | 1 | | 15MAY2020 10:45 |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10070 | 16MAY2020 19:00 | Induration/Swelling | Moderate | 1 | | 15MAY2020 10:45 |
| | | 17MAY2020 19:00 | Pain | Moderate | 2 | | 15MAY2020 10:45 |
| | | 17MAY2020 19:00 | Tenderness | Moderate | 2 | | 15MAY2020 10:45 |
| | | 17MAY2020 19:00 | Erythema/Redness | Mild | 2 | | 15MAY2020 10:45 |
| | | 17MAY2020 19:00 | Induration/Swelling | Moderate | 2 | | 15MAY2020 10:45 |
| | | 18MAY2020 19:15 | Tenderness | Mild | 3 | | 15MAY2020 10:45 |
| | | 18MAY2020 19:15 | Erythema/Redness | Moderate | 3 | | 15MAY2020 10:45 |
| | | 18MAY2020 19:15 | Induration/Swelling | Moderate | 3 | | 15MAY2020 10:45 |
| | | 19MAY2020 19:00 | Erythema/Redness | Moderate | 4 | | 15MAY2020 10:45 |
| | | 05JUN2020 19:00 | Pain | Severe | 21 | 0 | 15MAY2020 10:45 |
| | | 05JUN2020 19:00 | Tenderness | Moderate | 21 | 0 | 15MAY2020 10:45 |
| | | 06JUN2020 19:00 | Tenderness | Mild | 22 | 1 | 15MAY2020 10:45 |
| | | 07JUN2020 19:00 | Tenderness | Mild | 23 | 2 | 15MAY2020 10:45 |
| | 10073 | 16MAY2020 22:00 | Pain | Mild | 1 | | 15MAY2020 11:15 |
| | | 16MAY2020 22:00 | Tenderness | Mild | 1 | | 15MAY2020 11:15 |
| | | 05JUN2020 22:23 | Pain | Severe | 21 | 0 | 15MAY2020 11:15 |
| | | 05JUN2020 22:23 | Tenderness | Severe | 21 | 0 | 15MAY2020 11:15 |
| 06JUN2020 16:10 | | Pain | Severe | 22 | 1 | 15MAY2020 11:15 | |
| Program: Lsaf_locR_1.sas (Page 34 of 56) | | | | | | | |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10073 | 06JUN2020 16:10 | Tenderness | Severe | 22 | 1 | 15MAY2020 11:15 |
| | | 07JUN2020 22:46 | Pain | Severe | 23 | 2 | 15MAY2020 11:15 |
| | | 07JUN2020 22:46 | Tenderness | Severe | 23 | 2 | 15MAY2020 11:15 |
| | | 08JUN2020 23:20 | Pain | Moderate | 24 | 3 | 15MAY2020 11:15 |
| | | 08JUN2020 23:20 | Tenderness | Moderate | 24 | 3 | 15MAY2020 11:15 |
| | | 09JUN2020 1:04 | Pain | Mild | 25 | 4 | 15MAY2020 11:15 |
| 60 µg Younger | 10066 | 19MAY2020 21:55 | Pain | Moderate | 0 | | 19MAY2020 8:36 |
| | | 19MAY2020 21:55 | Tenderness | Moderate | 0 | | 19MAY2020 8:36 |
| | | 19MAY2020 21:55 | Induration/Swelling | Moderate | 0 | | 19MAY2020 8:36 |
| | | 20MAY2020 21:54 | Pain | Mild | 1 | | 19MAY2020 8:36 |
| | | 20MAY2020 21:54 | Tenderness | Moderate | 1 | | 19MAY2020 8:36 |
| | | 20MAY2020 21:54 | Induration/Swelling | Moderate | 1 | | 19MAY2020 8:36 |
| | | 21MAY2020 21:55 | Pain | Mild | 2 | | 19MAY2020 8:36 |
| | | 21MAY2020 21:55 | Tenderness | Mild | 2 | | 19MAY2020 8:36 |
| | | 21MAY2020 21:55 | Induration/Swelling | Mild | 2 | | 19MAY2020 8:36 |
| | | 22MAY2020 21:55 | Pain | Mild | 3 | | 19MAY2020 8:36 |
| | | 22MAY2020 21:55 | Tenderness | Mild | 3 | | 19MAY2020 8:36 |
| | | 22MAY2020 21:55 | Induration/Swelling | Mild | 3 | | 19MAY2020 8:36 |
| Program: Lsaf_locR_1.sas (Page 35 of 56) | | | | | | | |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 60 µg Younger | 10075 | 22MAY2020 22:05 | Pain | Severe | 0 | | 22MAY2020 8:50 |
| | | 22MAY2020 22:05 | Tenderness | Moderate | 0 | | 22MAY2020 8:50 |
| | | 23MAY2020 22:00 | Pain | Severe | 1 | | 22MAY2020 8:50 |
| | | 23MAY2020 22:00 | Tenderness | Moderate | 1 | | 22MAY2020 8:50 |
| | | 24MAY2020 22:00 | Pain | Mild | 2 | | 22MAY2020 8:50 |
| | | 24MAY2020 22:00 | Tenderness | Moderate | 2 | | 22MAY2020 8:50 |
| | | 25MAY2020 22:00 | Pain | Mild | 3 | | 22MAY2020 8:50 |
| | | 25MAY2020 22:00 | Tenderness | Mild | 3 | | 22MAY2020 8:50 |
| | | 26MAY2020 22:00 | Pain | Mild | 4 | | 22MAY2020 8:50 |
| | | 26MAY2020 22:00 | Tenderness | Mild | 4 | | 22MAY2020 8:50 |
| | | 27MAY2020 22:30 | Pain | Mild | 5 | | 22MAY2020 8:50 |
| | | 27MAY2020 22:30 | Tenderness | Mild | 5 | | 22MAY2020 8:50 |
| | 10076 | 22MAY2020 22:00 | Pain | Mild | 0 | | 22MAY2020 9:20 |
| | | 23MAY2020 22:00 | Pain | Mild | 1 | | 22MAY2020 9:20 |
| | 10078 | 22MAY2020 23:15 | Pain | Mild | 0 | | 22MAY2020 9:50 |
| | | 22MAY2020 23:15 | Tenderness | Mild | 0 | | 22MAY2020 9:50 |
| | | 23MAY2020 22:45 | Pain | Mild | 1 | | 22MAY2020 9:50 |
| | | 23MAY2020 22:45 | Tenderness | Moderate | 1 | | 22MAY2020 9:50 |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|---------------|--|-------------------------|----------------|---------------------|---|---|---------------------------------|--|
| 60 µg Younger | 10083 | 20MAY2020 19:21 | Pain | Mild | 0 | | 20MAY2020 9:15 | |
| | | 20MAY2020 19:21 | Tenderness | Mild | 0 | | 20MAY2020 9:15 | |
| | | 21MAY2020 18:45 | Pain | Mild | 1 | | 20MAY2020 9:15 | |
| | | 21MAY2020 18:45 | Tenderness | Mild | 1 | | 20MAY2020 9:15 | |
| | | 22MAY2020 20:00 | Pain | Mild | 2 | | 20MAY2020 9:15 | |
| | | 22MAY2020 20:00 | Tenderness | Mild | 2 | | 20MAY2020 9:15 | |
| | 10084 | 22MAY2020 20:30 | Pain | Mild | 0 | | 22MAY2020 10:20 | |
| | | 22MAY2020 20:30 | Tenderness | Mild | 0 | | 22MAY2020 10:20 | |
| | | 23MAY2020 20:30 | Tenderness | Mild | 1 | | 22MAY2020 10:20 | |
| | 10085 | 22MAY2020 23:00 | Pain | Mild | 0 | | 22MAY2020 10:50 | |
| | | 22MAY2020 23:00 | Tenderness | Moderate | 0 | | 22MAY2020 10:50 | |
| | | 23MAY2020 21:50 | Pain | Mild | 1 | | 22MAY2020 10:50 | |
| | | 23MAY2020 21:50 | Tenderness | Moderate | 1 | | 22MAY2020 10:50 | |
| | | 24MAY2020 22:15 | Pain | Mild | 2 | | 22MAY2020 10:50 | |
| | | 24MAY2020 22:15 | Tenderness | Mild | 2 | | 22MAY2020 10:50 | |
| | 10089 | 20MAY2020 22:00 | Pain | Mild | 0 | | 20MAY2020 9:45 | |
| | | 20MAY2020 22:00 | Tenderness | Moderate | 0 | | 20MAY2020 9:45 | |
| | | 21MAY2020 22:00 | Pain | Mild | 1 | | 20MAY2020 9:45 | |
| | Program: Lsaf_locR_1.sas (Page 37 of 56) | | | | | | | |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|---------------|--|-------------------------|----------------|---------------------|---|---|---------------------------------|--|
| 60 µg Younger | 10089 | 21MAY2020 22:00 | Tenderness | Moderate | 1 | | 20MAY2020 9:45 | |
| | | 22MAY2020 22:00 | Pain | Mild | 2 | | 20MAY2020 9:45 | |
| | | 22MAY2020 22:00 | Tenderness | Mild | 2 | | 20MAY2020 9:45 | |
| | | 23MAY2020 22:00 | Tenderness | Mild | 3 | | 20MAY2020 9:45 | |
| | 10093 | 20MAY2020 19:00 | Pain | Mild | 0 | | 20MAY2020 10:15 | |
| | | 21MAY2020 18:45 | Pain | Mild | 1 | | 20MAY2020 10:15 | |
| | | 21MAY2020 18:45 | Tenderness | Mild | 1 | | 20MAY2020 10:15 | |
| | 10096 | 19MAY2020 22:49 | Pain | Mild | 0 | | 19MAY2020 9:08 | |
| | | 19MAY2020 22:49 | Tenderness | Mild | 0 | | 19MAY2020 9:08 | |
| | | 20MAY2020 19:30 | Pain | Mild | 1 | | 19MAY2020 9:08 | |
| | | 20MAY2020 19:30 | Tenderness | Mild | 1 | | 19MAY2020 9:08 | |
| | 10103 | 22MAY2020 20:48 | Pain | Mild | 0 | | 22MAY2020 11:32 | |
| | | 22MAY2020 20:48 | Tenderness | Moderate | 0 | | 22MAY2020 11:32 | |
| | | 23MAY2020 15:18 | Pain | Mild | 1 | | 22MAY2020 11:32 | |
| | | 23MAY2020 15:18 | Tenderness | Mild | 1 | | 22MAY2020 11:32 | |
| | 10104 | 20MAY2020 22:00 | Pain | Mild | 0 | | 20MAY2020 10:45 | |
| | | 20MAY2020 22:00 | Tenderness | Moderate | 0 | | 20MAY2020 10:45 | |
| | | 21MAY2020 22:00 | Pain | Moderate | 1 | | 20MAY2020 10:45 | |
| | Program: Lsaf_locR_1.sas (Page 38 of 56) | | | | | | | |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | | |
|---------------|----------------|--|---------------------|---------------------|---|---|---------------------------------|--|--|
| 60 µg Younger | 10104 | 21MAY2020 22:00 | Tenderness | Moderate | 1 | | 20MAY2020 10:45 | | |
| | | 22MAY2020 22:00 | Pain | Mild | 2 | | 20MAY2020 10:45 | | |
| | | 22MAY2020 22:00 | Tenderness | Mild | 2 | | 20MAY2020 10:45 | | |
| | | 23MAY2020 23:00 | Pain | Mild | 3 | | 20MAY2020 10:45 | | |
| | | 23MAY2020 23:00 | Tenderness | Mild | 3 | | 20MAY2020 10:45 | | |
| | | 24MAY2020 22:00 | Tenderness | Mild | 4 | | 20MAY2020 10:45 | | |
| 10 µg Older | 10274 | 18SEP2020 20:00 | Tenderness | Mild | 22 | 1 | 27AUG2020 9:00 | | |
| | | 18SEP2020 20:00 | Erythema/Redness | Mild | 22 | 1 | 27AUG2020 9:00 | | |
| | | 18SEP2020 20:00 | Induration/Swelling | Mild | 22 | 1 | 27AUG2020 9:00 | | |
| | | 19SEP2020 21:00 | Tenderness | Mild | 23 | 2 | 27AUG2020 9:00 | | |
| | | 19SEP2020 21:00 | Erythema/Redness | Mild | 23 | 2 | 27AUG2020 9:00 | | |
| | | 20SEP2020 19:45 | Erythema/Redness | Mild | 24 | 3 | 27AUG2020 9:00 | | |
| | | 21SEP2020 20:15 | Erythema/Redness | Mild | 25 | 4 | 27AUG2020 9:00 | | |
| | | 22SEP2020 20:00 | Erythema/Redness | Mild | 26 | 5 | 27AUG2020 9:00 | | |
| | 10282 | 20AUG2020 18:50 | Pain | Mild | 0 | | 20AUG2020 9:33 | | |
| | | 20AUG2020 18:50 | Tenderness | Mild | 0 | | 20AUG2020 9:33 | | |
| | | 21AUG2020 19:00 | Pain | Mild | 1 | | 20AUG2020 9:33 | | |
| | | 21AUG2020 19:00 | Tenderness | Mild | 1 | | 20AUG2020 9:33 | | |
| | | Program: Lsaf_locR_1.sas (Page 39 of 56) | | | | | | | |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|-------------|--|-------------------------|----------------|---------------------|---|---|---------------------------------|--|
| 10 µg Older | 10282 | 10SEP2020 16:00 | Tenderness | Mild | 21 | 0 | 20AUG2020 9:33 | |
| | | 11SEP2020 18:00 | Pain | Mild | 22 | 1 | 20AUG2020 9:33 | |
| | 10283 | 27AUG2020 21:00 | Pain | Mild | 0 | | 27AUG2020 9:30 | |
| | | 27AUG2020 21:00 | Tenderness | Mild | 0 | | 27AUG2020 9:30 | |
| | | 28AUG2020 21:30 | Pain | Mild | 1 | | 27AUG2020 9:30 | |
| | | 28AUG2020 21:30 | Tenderness | Mild | 1 | | 27AUG2020 9:30 | |
| | | 17SEP2020 21:00 | Pain | Mild | 21 | 0 | 27AUG2020 9:30 | |
| | | 17SEP2020 21:00 | Tenderness | Mild | 21 | 0 | 27AUG2020 9:30 | |
| | | 18SEP2020 21:00 | Pain | Mild | 22 | 1 | 27AUG2020 9:30 | |
| | | 18SEP2020 21:00 | Tenderness | Mild | 22 | 1 | 27AUG2020 9:30 | |
| | 10286 | 25AUG2020 18:30 | Tenderness | Mild | 0 | | 25AUG2020 8:30 | |
| | | 26AUG2020 18:30 | Pain | Mild | 1 | | 25AUG2020 8:30 | |
| | | 26AUG2020 18:30 | Tenderness | Mild | 1 | | 25AUG2020 8:30 | |
| | | 15SEP2020 20:00 | Tenderness | Mild | 21 | 0 | 25AUG2020 8:30 | |
| | 10287 | 25AUG2020 21:00 | Pain | Mild | 0 | | 25AUG2020 9:00 | |
| | | 25AUG2020 21:00 | Tenderness | Mild | 0 | | 25AUG2020 9:00 | |
| | | 26AUG2020 0:00 | Tenderness | Mild | 1 | | 25AUG2020 9:00 | |
| | | 15SEP2020 23:10 | Pain | Moderate | 21 | 0 | 25AUG2020 9:00 | |
| | Program: Lsaf_locR_1.sas (Page 40 of 56) | | | | | | | |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-----------------|----------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 10 µg Older | 10287 | 15SEP2020 23:10 | Tenderness | Mild | 21 | 0 | 25AUG2020 9:00 |
| | | 16SEP2020 23:00 | Pain | Mild | 22 | 1 | 25AUG2020 9:00 |
| | | 16SEP2020 23:00 | Tenderness | Mild | 22 | 1 | 25AUG2020 9:00 |
| | | 17SEP2020 0:00 | Pain | Mild | 23 | 2 | 25AUG2020 9:00 |
| | | 17SEP2020 0:00 | Tenderness | Mild | 23 | 2 | 25AUG2020 9:00 |
| | | 18SEP2020 1:20 | Pain | Mild | 24 | 3 | 25AUG2020 9:00 |
| | | 18SEP2020 1:20 | Tenderness | Mild | 24 | 3 | 25AUG2020 9:00 |
| | | 19SEP2020 1:15 | Pain | Mild | 25 | 4 | 25AUG2020 9:00 |
| | | 19SEP2020 1:15 | Tenderness | Mild | 25 | 4 | 25AUG2020 9:00 |
| | | 20SEP2020 1:05 | Pain | Mild | 26 | 5 | 25AUG2020 9:00 |
| | 20SEP2020 1:05 | Tenderness | Mild | 26 | 5 | 25AUG2020 9:00 | |
| | 10288 | 25AUG2020 21:00 | Tenderness | Mild | 0 | | 25AUG2020 9:30 |
| | | 26AUG2020 21:00 | Pain | Mild | 1 | | 25AUG2020 9:30 |
| | | 26AUG2020 21:00 | Tenderness | Mild | 1 | | 25AUG2020 9:30 |
| | | 15SEP2020 23:00 | Pain | Mild | 21 | 0 | 25AUG2020 9:30 |
| | | 15SEP2020 23:00 | Tenderness | Mild | 21 | 0 | 25AUG2020 9:30 |
| | | 15SEP2020 23:00 | Induration/Swelling | Mild | 21 | 0 | 25AUG2020 9:30 |
| 16SEP2020 23:00 | | Pain | Mild | 22 | 1 | 25AUG2020 9:30 | |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 10 µg Older | 10288 | 16SEP2020 23:00 | Induration/Swelling | Mild | 22 | 1 | 25AUG2020 9:30 |
| | | 17SEP2020 23:00 | Induration/Swelling | Mild | 23 | 2 | 25AUG2020 9:30 |
| | | 18SEP2020 23:00 | Induration/Swelling | Mild | 24 | 3 | 25AUG2020 9:30 |
| | | 19SEP2020 23:00 | Erythema/Redness | Mild | 25 | 4 | 25AUG2020 9:30 |
| | | 19SEP2020 23:00 | Induration/Swelling | Mild | 25 | 4 | 25AUG2020 9:30 |
| | | 20SEP2020 23:00 | Erythema/Redness | Mild | 26 | 5 | 25AUG2020 9:30 |
| | | 20SEP2020 23:00 | Induration/Swelling | Mild | 26 | 5 | 25AUG2020 9:30 |
| | | 21SEP2020 23:00 | Erythema/Redness | Mild | 27 | 6 | 25AUG2020 9:30 |
| | | 21SEP2020 23:00 | Induration/Swelling | Mild | 27 | 6 | 25AUG2020 9:30 |
| | 10298 | 27AUG2020 20:15 | Pain | Mild | 0 | | 27AUG2020 10:30 |
| | | 27AUG2020 20:15 | Tenderness | Mild | 0 | | 27AUG2020 10:30 |
| | | 28AUG2020 20:08 | Pain | Mild | 1 | | 27AUG2020 10:30 |
| | | 28AUG2020 20:08 | Tenderness | Mild | 1 | | 27AUG2020 10:30 |
| | | 29AUG2020 20:10 | Pain | Mild | 2 | | 27AUG2020 10:30 |
| | | 29AUG2020 20:10 | Tenderness | Mild | 2 | | 27AUG2020 10:30 |
| | | 17SEP2020 1:00 | Pain | Mild | 21 | 0 | 27AUG2020 10:30 |
| | | 17SEP2020 1:00 | Tenderness | Moderate | 21 | 0 | 27AUG2020 10:30 |
| | | 18SEP2020 10:00 | Pain | Mild | 22 | 1 | 27AUG2020 10:30 |
| Program: Lsaf_locR_1.sas (Page 42 of 56) | | | | | | | |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-------------|-----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 10 µg Older | 10298 | 18SEP2020 10:00 | Tenderness | Moderate | 22 | 1 | 27AUG2020 10:30 |
| | | 19SEP2020 16:00 | Pain | Mild | 23 | 2 | 27AUG2020 10:30 |
| | | 19SEP2020 16:00 | Tenderness | Mild | 23 | 2 | 27AUG2020 10:30 |
| | | 20SEP2020 20:00 | Pain | Mild | 24 | 3 | 27AUG2020 10:30 |
| | | 20SEP2020 20:00 | Tenderness | Mild | 24 | 3 | 27AUG2020 10:30 |
| | | 21SEP2020 20:10 | Pain | Mild | 25 | 4 | 27AUG2020 10:30 |
| | | 21SEP2020 20:10 | Tenderness | Mild | 25 | 4 | 27AUG2020 10:30 |
| | | 22SEP2020 20:05 | Pain | Mild | 26 | 5 | 27AUG2020 10:30 |
| | | 22SEP2020 20:05 | Tenderness | Mild | 26 | 5 | 27AUG2020 10:30 |
| | 23SEP2020 20:10 | Tenderness | Mild | 27 | 6 | 27AUG2020 10:30 | |
| | 10320 | 27AUG2020 19:00 | Tenderness | Mild | 0 | | 27AUG2020 11:00 |
| | | 28AUG2020 19:00 | Tenderness | Mild | 1 | | 27AUG2020 11:00 |
| | | 17SEP2020 | Pain | Moderate | 21 | 0 | 27AUG2020 11:00 |
| | | 18SEP2020 10:00 | Pain | Moderate | 22 | 1 | 27AUG2020 11:00 |
| | | 18SEP2020 10:00 | Tenderness | Moderate | 22 | 1 | 27AUG2020 11:00 |
| | | 19SEP2020 10:00 | Pain | Moderate | 23 | 2 | 27AUG2020 11:00 |
| | | 19SEP2020 10:00 | Tenderness | Mild | 23 | 2 | 27AUG2020 11:00 |
| | | 20SEP2020 10:00 | Pain | Mild | 24 | 3 | 27AUG2020 11:00 |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-------------|-----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 10 µg Older | 10320 | 20SEP2020 10:00 | Tenderness | Mild | 24 | 3 | 27AUG2020 11:00 |
| | | 21SEP2020 10:00 | Pain | Mild | 25 | 4 | 27AUG2020 11:00 |
| | | 21SEP2020 10:00 | Tenderness | Mild | 25 | 4 | 27AUG2020 11:00 |
| | | 22SEP2020 10:30 | Pain | Mild | 26 | 5 | 27AUG2020 11:00 |
| | | 22SEP2020 10:30 | Tenderness | Mild | 26 | 5 | 27AUG2020 11:00 |
| | | 23SEP2020 10:00 | Tenderness | Mild | 27 | 6 | 27AUG2020 11:00 |
| 20 µg Older | 20207 | 09SEP2020 20:30 | Pain | Mild | 0 | | 09SEP2020 9:00 |
| | | 09SEP2020 20:30 | Tenderness | Mild | 0 | | 09SEP2020 9:00 |
| | | 10SEP2020 20:00 | Pain | Mild | 1 | | 09SEP2020 9:00 |
| | | 10SEP2020 20:00 | Tenderness | Mild | 1 | | 09SEP2020 9:00 |
| | | 30SEP2020 19:00 | Tenderness | Mild | 21 | 0 | 09SEP2020 9:00 |
| | | 01OCT2020 20:00 | Pain | Mild | 22 | 1 | 09SEP2020 9:00 |
| | | 01OCT2020 20:00 | Tenderness | Mild | 22 | 1 | 09SEP2020 9:00 |
| | | 02OCT2020 20:30 | Pain | Mild | 23 | 2 | 09SEP2020 9:00 |
| | 02OCT2020 20:30 | Tenderness | Mild | 23 | 2 | 09SEP2020 9:00 | |
| | 20211 | 08SEP2020 20:30 | Tenderness | Mild | 0 | | 08SEP2020 8:00 |
| | | 09SEP2020 20:30 | Pain | Mild | 1 | | 08SEP2020 8:00 |
| | | 09SEP2020 20:30 | Tenderness | Mild | 1 | | 08SEP2020 8:00 |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 20 µg Older | 20211 | 10SEP2020 20:30 | Pain | Mild | 2 | | 08SEP2020 8:00 |
| | | 10SEP2020 20:30 | Tenderness | Mild | 2 | | 08SEP2020 8:00 |
| | | 30SEP2020 19:30 | Pain | Mild | 22 | 0 | 08SEP2020 8:00 |
| | | 30SEP2020 19:30 | Tenderness | Mild | 22 | 0 | 08SEP2020 8:00 |
| | 20220 | 08SEP2020 21:00 | Tenderness | Mild | 0 | | 08SEP2020 9:00 |
| | | 08SEP2020 21:00 | Induration/Swelling | Mild | 0 | | 08SEP2020 9:00 |
| | | 09SEP2020 21:00 | Tenderness | Mild | 1 | | 08SEP2020 9:00 |
| | | 09SEP2020 21:00 | Induration/Swelling | Mild | 1 | | 08SEP2020 9:00 |
| | | 30SEP2020 20:00 | Pain | Mild | 22 | 0 | 08SEP2020 9:00 |
| | | 30SEP2020 20:00 | Tenderness | Mild | 22 | 0 | 08SEP2020 9:00 |
| | | 01OCT2020 21:00 | Pain | Mild | 23 | 1 | 08SEP2020 9:00 |
| | | 01OCT2020 21:00 | Tenderness | Mild | 23 | 1 | 08SEP2020 9:00 |
| | | 01OCT2020 21:00 | Induration/Swelling | Mild | 23 | 1 | 08SEP2020 9:00 |
| | | 02OCT2020 21:00 | Pain | Mild | 24 | 2 | 08SEP2020 9:00 |
| | | 02OCT2020 21:00 | Tenderness | Mild | 24 | 2 | 08SEP2020 9:00 |
| | | 03OCT2020 20:00 | Pain | Mild | 25 | 3 | 08SEP2020 9:00 |
| | | 03OCT2020 20:00 | Tenderness | Mild | 25 | 3 | 08SEP2020 9:00 |
| | | 04OCT2020 20:00 | Tenderness | Mild | 26 | 4 | 08SEP2020 9:00 |
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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|-------------|--|-------------------------|---------------------|---------------------|---|---|---------------------------------|--|
| 20 µg Older | 20220 | 05OCT2020 21:00 | Tenderness | Mild | 27 | 5 | 08SEP2020 9:00 | |
| | 20227 | 12SEP2020 22:10 | Tenderness | Moderate | 1 | | 11SEP2020 11:30 | |
| | | 02OCT2020 22:15 | Pain | Mild | 21 | 0 | 11SEP2020 11:30 | |
| | | 02OCT2020 22:15 | Tenderness | Mild | 21 | 0 | 11SEP2020 11:30 | |
| | | 03OCT2020 20:00 | Pain | Moderate | 22 | 1 | 11SEP2020 11:30 | |
| | | 03OCT2020 20:00 | Tenderness | Moderate | 22 | 1 | 11SEP2020 11:30 | |
| | | 03OCT2020 20:00 | Induration/Swelling | Mild | 22 | 1 | 11SEP2020 11:30 | |
| | | 04OCT2020 21:50 | Pain | Moderate | 23 | 2 | 11SEP2020 11:30 | |
| | | 04OCT2020 21:50 | Tenderness | Moderate | 23 | 2 | 11SEP2020 11:30 | |
| | | 04OCT2020 21:50 | Induration/Swelling | Mild | 23 | 2 | 11SEP2020 11:30 | |
| | | 05OCT2020 22:00 | Pain | Mild | 24 | 3 | 11SEP2020 11:30 | |
| | | 05OCT2020 22:00 | Tenderness | Mild | 24 | 3 | 11SEP2020 11:30 | |
| | 20234 | 10SEP2020 21:00 | Pain | Mild | 1 | | 09SEP2020 9:30 | |
| | | 11SEP2020 21:15 | Pain | Mild | 2 | | 09SEP2020 9:30 | |
| | | 12SEP2020 21:00 | Pain | Mild | 3 | | 09SEP2020 9:30 | |
| | | 30SEP2020 21:30 | Pain | Mild | 21 | 0 | 09SEP2020 9:30 | |
| | | 01OCT2020 21:00 | Pain | Mild | 22 | 1 | 09SEP2020 9:30 | |
| | 20236 | 11SEP2020 21:46 | Tenderness | Mild | 0 | | 11SEP2020 10:30 | |
| | Program: Lsaf_locR_1.sas (Page 46 of 56) | | | | | | | |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|-------------|--|-------------------------|---------------------|---------------------|---|---|---------------------------------|--|
| 20 µg Older | 20236 | 12SEP2020 21:46 | Tenderness | Mild | 1 | | 11SEP2020 10:30 | |
| | 20237 | 11SEP2020 22:00 | Pain | Moderate | 0 | | 11SEP2020 9:00 | |
| | | 11SEP2020 22:00 | Tenderness | Moderate | 0 | | 11SEP2020 9:00 | |
| | | 12SEP2020 22:15 | Pain | Mild | 1 | | 11SEP2020 9:00 | |
| | | 12SEP2020 22:15 | Tenderness | Mild | 1 | | 11SEP2020 9:00 | |
| | | 02OCT2020 22:30 | Pain | Mild | 21 | 0 | 11SEP2020 9:00 | |
| | | 02OCT2020 22:30 | Tenderness | Mild | 21 | 0 | 11SEP2020 9:00 | |
| | | 03OCT2020 23:00 | Pain | Mild | 22 | 1 | 11SEP2020 9:00 | |
| | | 03OCT2020 23:00 | Tenderness | Mild | 22 | 1 | 11SEP2020 9:00 | |
| | | 04OCT2020 22:30 | Pain | Mild | 23 | 2 | 11SEP2020 9:00 | |
| | | 04OCT2020 22:30 | Tenderness | Mild | 23 | 2 | 11SEP2020 9:00 | |
| | 20238 | 11SEP2020 19:45 | Tenderness | Moderate | 0 | | 11SEP2020 10:00 | |
| | | 11SEP2020 19:45 | Induration/Swelling | Mild | 0 | | 11SEP2020 10:00 | |
| | | 12SEP2020 19:30 | Tenderness | Mild | 1 | | 11SEP2020 10:00 | |
| | | 02OCT2020 21:12 | Pain | Mild | 21 | 0 | 11SEP2020 10:00 | |
| | | 02OCT2020 21:12 | Tenderness | Mild | 21 | 0 | 11SEP2020 10:00 | |
| | | 02OCT2020 21:12 | Induration/Swelling | Mild | 21 | 0 | 11SEP2020 10:00 | |
| | 20239 | 11SEP2020 22:00 | Pain | Mild | 0 | | 11SEP2020 11:00 | |
| | Program: Lsaf_locR_1.sas (Page 47 of 56) | | | | | | | |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-------------|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 20 µg Older | 20239 | 11SEP2020 22:00 | Tenderness | Moderate | 0 | | 11SEP2020 11:00 |
| | | 12SEP2020 22:00 | Pain | Mild | 1 | | 11SEP2020 11:00 |
| | | 12SEP2020 22:00 | Tenderness | Moderate | 1 | | 11SEP2020 11:00 |
| | | 02OCT2020 19:30 | Tenderness | Mild | 21 | 0 | 11SEP2020 11:00 |
| | | 03OCT2020 20:00 | Tenderness | Moderate | 22 | 1 | 11SEP2020 11:00 |
| | | 04OCT2020 20:00 | Tenderness | Moderate | 23 | 2 | 11SEP2020 11:00 |
| | 20241 | 09SEP2020 21:45 | Pain | Mild | 0 | | 09SEP2020 10:30 |
| | | 09SEP2020 21:45 | Tenderness | Mild | 0 | | 09SEP2020 10:30 |
| | | 10SEP2020 21:45 | Pain | Mild | 1 | | 09SEP2020 10:30 |
| | | 10SEP2020 21:45 | Tenderness | Mild | 1 | | 09SEP2020 10:30 |
| | | 11SEP2020 21:45 | Pain | Mild | 2 | | 09SEP2020 10:30 |
| | | 11SEP2020 21:45 | Tenderness | Mild | 2 | | 09SEP2020 10:30 |
| | | 12SEP2020 21:45 | Tenderness | Mild | 3 | | 09SEP2020 10:30 |
| | | 30SEP2020 20:00 | Pain | Mild | 21 | 0 | 09SEP2020 10:30 |
| | | 01OCT2020 9:30 | Pain | Mild | 22 | 1 | 09SEP2020 10:30 |
| | | 02OCT2020 9:30 | Pain | Mild | 23 | 2 | 09SEP2020 10:30 |
| | | 03OCT2020 9:30 | Pain | Mild | 24 | 3 | 09SEP2020 10:30 |
| | | 03OCT2020 9:30 | Tenderness | Mild | 24 | 3 | 09SEP2020 10:30 |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 20 µg Older | 20241 | 04OCT2020 9:30 | Pain | Mild | 25 | 4 | 09SEP2020 10:30 |
| | | 04OCT2020 9:30 | Tenderness | Moderate | 25 | 4 | 09SEP2020 10:30 |
| | | 05OCT2020 9:30 | Pain | Mild | 26 | 5 | 09SEP2020 10:30 |
| | | 05OCT2020 9:30 | Tenderness | Moderate | 26 | 5 | 09SEP2020 10:30 |
| | | 06OCT2020 9:30 | Pain | Mild | 27 | 6 | 09SEP2020 10:30 |
| | | 06OCT2020 9:30 | Tenderness | Mild | 27 | 6 | 09SEP2020 10:30 |
| | | 07OCT2020 9:07 | Pain | Mild | 28 | 7 | 09SEP2020 10:30 |
| | | 07OCT2020 9:07 | Tenderness | Mild | 28 | 7 | 09SEP2020 10:30 |
| | 20242 | 09SEP2020 22:00 | Pain | Mild | 0 | | 09SEP2020 10:00 |
| | | 10SEP2020 23:00 | Pain | Mild | 1 | | 09SEP2020 10:00 |
| | | 10SEP2020 23:00 | Tenderness | Mild | 1 | | 09SEP2020 10:00 |
| | | 11SEP2020 22:30 | Pain | Mild | 2 | | 09SEP2020 10:00 |
| | | 11SEP2020 22:30 | Tenderness | Mild | 2 | | 09SEP2020 10:00 |
| | | 12SEP2020 23:00 | Pain | Mild | 3 | | 09SEP2020 10:00 |
| | | 12SEP2020 23:00 | Tenderness | Mild | 3 | | 09SEP2020 10:00 |
| 13SEP2020 22:30 | | Pain | Mild | 4 | | 09SEP2020 10:00 | |
| 13SEP2020 22:30 | Tenderness | Mild | 4 | | 09SEP2020 10:00 | | |
| 30 µg Older | 10350 | 25SEP2020 20:00 | Pain | Mild | 0 | | 25SEP2020 8:20 |
| Program: Lsaf_locR_1.sas (Page 49 of 56) | | | | | | | |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 30 µg Older | 10350 | 25SEP2020 20:00 | Tenderness | Mild | 0 | | 25SEP2020 8:20 |
| | | 26SEP2020 20:00 | Pain | Mild | 1 | | 25SEP2020 8:20 |
| | | 26SEP2020 20:00 | Tenderness | Mild | 1 | | 25SEP2020 8:20 |
| | | 16OCT2020 20:00 | Pain | Moderate | 21 | 0 | 25SEP2020 8:20 |
| | | 16OCT2020 20:00 | Tenderness | Moderate | 21 | 0 | 25SEP2020 8:20 |
| | | 17OCT2020 20:00 | Pain | Mild | 22 | 1 | 25SEP2020 8:20 |
| | | 17OCT2020 20:00 | Tenderness | Mild | 22 | 1 | 25SEP2020 8:20 |
| | | 18OCT2020 20:00 | Pain | Mild | 23 | 2 | 25SEP2020 8:20 |
| | | 18OCT2020 20:00 | Tenderness | Mild | 23 | 2 | 25SEP2020 8:20 |
| | 10351 | 25SEP2020 20:45 | Pain | Mild | 0 | | 25SEP2020 8:50 |
| | | 25SEP2020 20:45 | Tenderness | Moderate | 0 | | 25SEP2020 8:50 |
| | | 26SEP2020 21:40 | Pain | Mild | 1 | | 25SEP2020 8:50 |
| | | 26SEP2020 21:40 | Tenderness | Mild | 1 | | 25SEP2020 8:50 |
| | | 16OCT2020 8:50 | Pain | Moderate | 21 | 0 | 25SEP2020 8:50 |
| | | 16OCT2020 8:50 | Tenderness | Moderate | 21 | 0 | 25SEP2020 8:50 |
| | | 16OCT2020 21:00 | Pain | Moderate | 21 | 0 | 25SEP2020 8:50 |
| | | 16OCT2020 21:00 | Tenderness | Moderate | 21 | 0 | 25SEP2020 8:50 |
| | | 17OCT2020 21:00 | Pain | Moderate | 22 | 1 | 25SEP2020 8:50 |
| Program: Lsaf_locR_1.sas (Page 50 of 56) | | | | | | | |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 30 µg Older | 10351 | 17OCT2020 21:00 | Tenderness | Moderate | 22 | 1 | 25SEP2020 8:50 |
| | | 18OCT2020 21:00 | Pain | Mild | 23 | 2 | 25SEP2020 8:50 |
| | | 18OCT2020 21:00 | Tenderness | Mild | 23 | 2 | 25SEP2020 8:50 |
| | 10353 | 22SEP2020 19:00 | Pain | Mild | 0 | | 22SEP2020 8:50 |
| | | 22SEP2020 19:00 | Tenderness | Mild | 0 | | 22SEP2020 8:50 |
| | | 22SEP2020 19:00 | Induration/Swelling | Mild | 0 | | 22SEP2020 8:50 |
| | | 23SEP2020 19:00 | Pain | Mild | 1 | | 22SEP2020 8:50 |
| | | 23SEP2020 19:00 | Tenderness | Mild | 1 | | 22SEP2020 8:50 |
| | | 23SEP2020 19:00 | Induration/Swelling | Mild | 1 | | 22SEP2020 8:50 |
| | | 24SEP2020 20:00 | Pain | Mild | 2 | | 22SEP2020 8:50 |
| | | 24SEP2020 20:00 | Tenderness | Mild | 2 | | 22SEP2020 8:50 |
| | | 24SEP2020 20:00 | Induration/Swelling | Mild | 2 | | 22SEP2020 8:50 |
| | | 25SEP2020 20:00 | Pain | Mild | 3 | | 22SEP2020 8:50 |
| | | 25SEP2020 20:00 | Tenderness | Mild | 3 | | 22SEP2020 8:50 |
| | | 26SEP2020 20:00 | Tenderness | Mild | 4 | | 22SEP2020 8:50 |
| | | 13OCT2020 20:00 | Pain | Moderate | 21 | 0 | 22SEP2020 8:50 |
| | | 13OCT2020 20:00 | Tenderness | Moderate | 21 | 0 | 22SEP2020 8:50 |
| | | 14OCT2020 22:00 | Pain | Moderate | 22 | 1 | 22SEP2020 8:50 |
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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|---------------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 30 µg Older | 10353 | 14OCT2020 22:00 | Tenderness | Moderate | 22 | 1 | 22SEP2020 8:50 |
| | 10358 | 23SEP2020 19:30 | Pain | Mild | 0 | | 23SEP2020 8:31 |
| | | 23SEP2020 19:30 | Tenderness | Mild | 0 | | 23SEP2020 8:31 |
| | | 24SEP2020 19:30 | Pain | Moderate | 1 | | 23SEP2020 8:31 |
| | | 24SEP2020 19:30 | Tenderness | Moderate | 1 | | 23SEP2020 8:31 |
| | | 14OCT2020 | Pain | Mild | 21 | 0 | 23SEP2020 8:31 |
| | | 14OCT2020 | Tenderness | Mild | 21 | 0 | 23SEP2020 8:31 |
| | | 15OCT2020 19:00 | Pain | Mild | 22 | 1 | 23SEP2020 8:31 |
| | | 15OCT2020 19:00 | Tenderness | Mild | 22 | 1 | 23SEP2020 8:31 |
| | | 16OCT2020 18:30 | Pain | Mild | 23 | 2 | 23SEP2020 8:31 |
| | | 16OCT2020 18:30 | Tenderness | Mild | 23 | 2 | 23SEP2020 8:31 |
| | | 16OCT2020 18:30 | Erythema/Redness | Mild | 23 | 2 | 23SEP2020 8:31 |
| | | 17OCT2020 18:30 | Pain | Mild | 24 | 3 | 23SEP2020 8:31 |
| | | 17OCT2020 18:30 | Tenderness | Mild | 24 | 3 | 23SEP2020 8:31 |
| | | 17OCT2020 18:30 | Induration/Swelling | Mild | 24 | 3 | 23SEP2020 8:31 |
| | | 18OCT2020 19:30 | Pain | Mild | 25 | 4 | 23SEP2020 8:31 |
| | | 18OCT2020 19:30 | Tenderness | Mild | 25 | 4 | 23SEP2020 8:31 |
| 18OCT2020 19:30 | Induration/Swelling | Mild | 25 | 4 | 23SEP2020 8:31 | | |
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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-------------|----------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 30 µg Older | 10358 | 19OCT2020 19:00 | Pain | Mild | 26 | 5 | 23SEP2020 8:31 |
| | | 19OCT2020 19:00 | Tenderness | Mild | 26 | 5 | 23SEP2020 8:31 |
| | | 19OCT2020 19:00 | Induration/Swelling | Mild | 26 | 5 | 23SEP2020 8:31 |
| | | 20OCT2020 18:30 | Pain | Mild | 27 | 6 | 23SEP2020 8:31 |
| | | 20OCT2020 18:30 | Tenderness | Mild | 27 | 6 | 23SEP2020 8:31 |
| | | 20OCT2020 18:30 | Induration/Swelling | Mild | 27 | 6 | 23SEP2020 8:31 |
| | 10360 | 23SEP2020 21:00 | Pain | Mild | 0 | | 23SEP2020 9:00 |
| | | 23SEP2020 21:00 | Tenderness | Mild | 0 | | 23SEP2020 9:00 |
| | | 24SEP2020 21:15 | Pain | Mild | 1 | | 23SEP2020 9:00 |
| | | 24SEP2020 21:15 | Tenderness | Mild | 1 | | 23SEP2020 9:00 |
| | | 25SEP2020 22:00 | Pain | Mild | 2 | | 23SEP2020 9:00 |
| | | 25SEP2020 22:00 | Tenderness | Mild | 2 | | 23SEP2020 9:00 |
| | | 14OCT2020 22:00 | Pain | Mild | 21 | 0 | 23SEP2020 9:00 |
| | | 14OCT2020 22:00 | Tenderness | Mild | 21 | 0 | 23SEP2020 9:00 |
| | | 15OCT2020 21:30 | Pain | Mild | 22 | 1 | 23SEP2020 9:00 |
| | | 15OCT2020 21:30 | Tenderness | Mild | 22 | 1 | 23SEP2020 9:00 |
| | 10361 | 25SEP2020 22:30 | Pain | Mild | 0 | | 25SEP2020 9:20 |
| | | 25SEP2020 22:30 | Tenderness | Mild | 0 | | 25SEP2020 9:20 |

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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|-------------|--|-------------------------|----------------|---------------------|---|---|---------------------------------|--|
| 30 µg Older | 10361 | 26SEP2020 22:15 | Pain | Mild | 1 | | 25SEP2020 9:20 | |
| | | 26SEP2020 22:15 | Tenderness | Mild | 1 | | 25SEP2020 9:20 | |
| | | 27SEP2020 23:00 | Tenderness | Mild | 2 | | 25SEP2020 9:20 | |
| | | 16OCT2020 22:30 | Pain | Moderate | 21 | 0 | 25SEP2020 9:20 | |
| | | 16OCT2020 22:30 | Tenderness | Moderate | 21 | 0 | 25SEP2020 9:20 | |
| | | 17OCT2020 23:00 | Pain | Mild | 22 | 1 | 25SEP2020 9:20 | |
| | | 17OCT2020 23:00 | Tenderness | Moderate | 22 | 1 | 25SEP2020 9:20 | |
| | | 18OCT2020 23:30 | Tenderness | Mild | 23 | 2 | 25SEP2020 9:20 | |
| | 10362 | 26SEP2020 20:45 | Pain | Mild | 1 | | 25SEP2020 9:50 | |
| | | 26SEP2020 20:45 | Tenderness | Mild | 1 | | 25SEP2020 9:50 | |
| | | 27SEP2020 20:45 | Tenderness | Mild | 2 | | 25SEP2020 9:50 | |
| | 10363 | 25SEP2020 21:30 | Tenderness | Moderate | 0 | | 25SEP2020 10:20 | |
| | | 26SEP2020 21:30 | Tenderness | Moderate | 1 | | 25SEP2020 10:20 | |
| | | 16OCT2020 21:45 | Pain | Mild | 21 | 0 | 25SEP2020 10:20 | |
| | | 16OCT2020 21:45 | Tenderness | Mild | 21 | 0 | 25SEP2020 10:20 | |
| | | 17OCT2020 21:45 | Pain | Mild | 22 | 1 | 25SEP2020 10:20 | |
| | | 17OCT2020 21:45 | Tenderness | Moderate | 22 | 1 | 25SEP2020 10:20 | |
| | 10364 | 25SEP2020 22:00 | Tenderness | Mild | 0 | | 25SEP2020 10:50 | |
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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 30 µg Older | 10364 | 26SEP2020 22:00 | Tenderness | Mild | 1 | | 25SEP2020 10:50 |
| | | 16OCT2020 21:30 | Tenderness | Mild | 21 | 0 | 25SEP2020 10:50 |
| | | 17OCT2020 21:00 | Tenderness | Moderate | 22 | 1 | 25SEP2020 10:50 |
| | | 18OCT2020 20:30 | Tenderness | Mild | 23 | 2 | 25SEP2020 10:50 |
| | 10365 | 23SEP2020 20:00 | Pain | Mild | 0 | | 23SEP2020 9:43 |
| | | 23SEP2020 20:00 | Tenderness | Mild | 0 | | 23SEP2020 9:43 |
| | | 24SEP2020 20:00 | Pain | Mild | 1 | | 23SEP2020 9:43 |
| | | 24SEP2020 20:00 | Tenderness | Mild | 1 | | 23SEP2020 9:43 |
| | | 25SEP2020 20:00 | Pain | Mild | 2 | | 23SEP2020 9:43 |
| | | 25SEP2020 20:00 | Tenderness | Mild | 2 | | 23SEP2020 9:43 |
| | | 14OCT2020 21:00 | Pain | Mild | 21 | 0 | 23SEP2020 9:43 |
| | | 14OCT2020 21:00 | Tenderness | Mild | 21 | 0 | 23SEP2020 9:43 |
| | | 15OCT2020 21:00 | Pain | Mild | 22 | 1 | 23SEP2020 9:43 |
| | | 15OCT2020 21:00 | Tenderness | Mild | 22 | 1 | 23SEP2020 9:43 |
| | | 16OCT2020 21:00 | Pain | Mild | 23 | 2 | 23SEP2020 9:43 |
| | | 16OCT2020 21:00 | Tenderness | Mild | 23 | 2 | 23SEP2020 9:43 |
| | | 16OCT2020 21:00 | Erythema/Redness | Mild | 23 | 2 | 23SEP2020 9:43 |
| | | 16OCT2020 21:00 | Induration/Swelling | Mild | 23 | 2 | 23SEP2020 9:43 |
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Listing 16.2.3-1.1-1: Listing of solicited local reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|------------------|---------------------|---|---|---------------------------------|
| 30 µg Older | 10365 | 17OCT2020 21:30 | Pain | Mild | 24 | 3 | 23SEP2020 9:43 |
| | | 17OCT2020 21:30 | Tenderness | Mild | 24 | 3 | 23SEP2020 9:43 |
| | | 17OCT2020 21:30 | Erythema/Redness | Mild | 24 | 3 | 23SEP2020 9:43 |
| | | 18OCT2020 21:00 | Erythema/Redness | Mild | 25 | 4 | 23SEP2020 9:43 |
| | 10366 | 23SEP2020 21:00 | Pain | Mild | 0 | | 23SEP2020 10:13 |
| Program: Lsaf_locR_1.sas (Page 56 of 56) | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---|-----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 1 µg Younger | 10015 | 29APR2020 23:00 | Headache | Mild | 0 | | 29APR2020 9:23 |
| | | 29APR2020 23:00 | Fatigue | Mild | 0 | | 29APR2020 9:23 |
| | | 20MAY2020 23:00 | Headache | Moderate | 21 | 0 | 29APR2020 9:23 |
| | 10018 | 29APR2020 | Headache | Mild | 0 | | 29APR2020 9:53 |
| | | 29APR2020 | Fatigue | Mild | 0 | | 29APR2020 9:53 |
| | 10025 | 05MAY2020 20:45 | Fatigue | Mild | 0 | | 05MAY2020 9:06 |
| | | 05MAY2020 20:45 | Chills | Mild | 0 | | 05MAY2020 9:06 |
| | | 26MAY2020 22:00 | Headache | Mild | 21 | 0 | 05MAY2020 9:06 |
| | | 26MAY2020 22:00 | Fatigue | Mild | 21 | 0 | 05MAY2020 9:06 |
| | | 26MAY2020 22:00 | Myalgia | Mild | 21 | 0 | 05MAY2020 9:06 |
| | | 26MAY2020 22:00 | Chills | Mild | 21 | 0 | 05MAY2020 9:06 |
| | | 27MAY2020 22:00 | Headache | Mild | 22 | 1 | 05MAY2020 9:06 |
| | | 27MAY2020 22:00 | Fatigue | Moderate | 22 | 1 | 05MAY2020 9:06 |
| | | 28MAY2020 21:00 | Fatigue | Moderate | 23 | 2 | 05MAY2020 9:06 |
| | | 29MAY2020 22:00 | Fatigue | Mild | 24 | 3 | 05MAY2020 9:06 |
| | 30MAY2020 22:00 | Fatigue | Mild | 25 | 4 | 05MAY2020 9:06 | |
| | 10033 | 27MAY2020 20:00 | Headache | Mild | 22 | 1 | 05MAY2020 10:03 |
| 27MAY2020 20:00 | | Fatigue | Moderate | 22 | 1 | 05MAY2020 10:03 | |
| Program: Lsaf_sysR_1.sas (Page 1 of 92) | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 1 µg Younger | 10033 | 27MAY2020 20:00 | Myalgia | Mild | 22 | 1 | 05MAY2020 10:03 |
| | | 27MAY2020 20:00 | Arthralgia | Mild | 22 | 1 | 05MAY2020 10:03 |
| | | 27MAY2020 20:00 | Chills | Mild | 22 | 1 | 05MAY2020 10:03 |
| | 10036 | 29MAY2020 18:00 | Headache | Moderate | 21 | 0 | 08MAY2020 8:30 |
| | | 29MAY2020 18:00 | Myalgia | Moderate | 21 | 0 | 08MAY2020 8:30 |
| | | 29MAY2020 18:00 | Chills | Moderate | 21 | 0 | 08MAY2020 8:30 |
| | | 29MAY2020 18:00 | Fever | Severe | 21 | 0 | 08MAY2020 8:30 |
| | | 30MAY2020 18:00 | Headache | Moderate | 22 | 1 | 08MAY2020 8:30 |
| | 10040 | 08MAY2020 20:32 | Fatigue | Mild | 0 | | 08MAY2020 8:51 |
| | | 09MAY2020 21:23 | Fatigue | Mild | 1 | | 08MAY2020 8:51 |
| | | 13MAY2020 21:49 | Headache | Mild | 5 | | 08MAY2020 8:51 |
| | | 13MAY2020 21:49 | Fatigue | Mild | 5 | | 08MAY2020 8:51 |
| | | 13MAY2020 21:49 | Myalgia | Mild | 5 | | 08MAY2020 8:51 |
| | | 13MAY2020 21:49 | Malaise | Moderate | 5 | | 08MAY2020 8:51 |
| | | 29MAY2020 22:12 | Headache | Moderate | 21 | 0 | 08MAY2020 8:51 |
| 29MAY2020 22:12 | | Fatigue | Moderate | 21 | 0 | 08MAY2020 8:51 | |
| 29MAY2020 22:12 | | Loss of Appetite | Mild | 21 | 0 | 08MAY2020 8:51 | |
| 29MAY2020 22:12 | Malaise | Mild | 21 | 0 | 08MAY2020 8:51 | | |
| Program: Lsaf_sysR_1.sas (Page 2 of 92) | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 1 µg Younger | 10040 | 30MAY2020 21:19 | Nausea | Mild | 22 | 1 | 08MAY2020 8:51 |
| | | 30MAY2020 21:19 | Headache | Moderate | 22 | 1 | 08MAY2020 8:51 |
| | | 30MAY2020 21:19 | Fatigue | Moderate | 22 | 1 | 08MAY2020 8:51 |
| | | 30MAY2020 21:19 | Myalgia | Moderate | 22 | 1 | 08MAY2020 8:51 |
| | | 30MAY2020 21:19 | Arthralgia | Moderate | 22 | 1 | 08MAY2020 8:51 |
| | | 30MAY2020 21:19 | Loss of Appetite | Mild | 22 | 1 | 08MAY2020 8:51 |
| | | 30MAY2020 21:19 | Malaise | Moderate | 22 | 1 | 08MAY2020 8:51 |
| | | 31MAY2020 21:05 | Headache | Moderate | 23 | 2 | 08MAY2020 8:51 |
| | | 31MAY2020 21:05 | Fatigue | Severe | 23 | 2 | 08MAY2020 8:51 |
| | | 31MAY2020 21:05 | Myalgia | Moderate | 23 | 2 | 08MAY2020 8:51 |
| | | 31MAY2020 21:05 | Loss of Appetite | Mild | 23 | 2 | 08MAY2020 8:51 |
| | | 31MAY2020 21:05 | Malaise | Moderate | 23 | 2 | 08MAY2020 8:51 |
| | | 01JUN2020 21:10 | Nausea | Mild | 24 | 3 | 08MAY2020 8:51 |
| | | 01JUN2020 21:10 | Headache | Mild | 24 | 3 | 08MAY2020 8:51 |
| | | 01JUN2020 21:10 | Fatigue | Moderate | 24 | 3 | 08MAY2020 8:51 |
| | | 01JUN2020 21:10 | Myalgia | Mild | 24 | 3 | 08MAY2020 8:51 |
| | | 01JUN2020 21:10 | Arthralgia | Mild | 24 | 3 | 08MAY2020 8:51 |
| | | 01JUN2020 21:10 | Loss of Appetite | Mild | 24 | 3 | 08MAY2020 8:51 |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--------------|---|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 1 µg Younger | 10040 | 01JUN2020 21:10 | Malaise | Mild | 24 | 3 | 08MAY2020 8:51 |
| | | 02JUN2020 21:00 | Nausea | Mild | 25 | 4 | 08MAY2020 8:51 |
| | | 02JUN2020 21:00 | Headache | Moderate | 25 | 4 | 08MAY2020 8:51 |
| | | 02JUN2020 21:00 | Fatigue | Mild | 25 | 4 | 08MAY2020 8:51 |
| | | 02JUN2020 21:00 | Myalgia | Moderate | 25 | 4 | 08MAY2020 8:51 |
| | | 02JUN2020 21:00 | Arthralgia | Moderate | 25 | 4 | 08MAY2020 8:51 |
| | | 02JUN2020 21:00 | Loss of Appetite | Mild | 25 | 4 | 08MAY2020 8:51 |
| | | 02JUN2020 21:00 | Malaise | Mild | 25 | 4 | 08MAY2020 8:51 |
| | | 03JUN2020 21:15 | Headache | Mild | 26 | 5 | 08MAY2020 8:51 |
| | | 03JUN2020 21:15 | Fatigue | Mild | 26 | 5 | 08MAY2020 8:51 |
| | | 03JUN2020 21:15 | Myalgia | Mild | 26 | 5 | 08MAY2020 8:51 |
| | | 03JUN2020 21:15 | Arthralgia | Mild | 26 | 5 | 08MAY2020 8:51 |
| | | 10041 | 08MAY2020 20:31 | Diarrhea | Mild | 0 | |
| | 09MAY2020 21:23 | | Fatigue | Mild | 1 | | 08MAY2020 9:06 |
| | 10MAY2020 21:28 | | Fatigue | Mild | 2 | | 08MAY2020 9:06 |
| | 11MAY2020 21:17 | | Fatigue | Mild | 3 | | 08MAY2020 9:06 |
| | 13MAY2020 21:50 | | Fatigue | Mild | 5 | | 08MAY2020 9:06 |
| | 13MAY2020 21:50 | | Chills | Mild | 5 | | 08MAY2020 9:06 |
| | Program: Lsaf_sysR_1.sas (Page 4 of 92) | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 1 µg Younger | 10041 | 13MAY2020 21:50 | Malaise | Mild | 5 | | 08MAY2020 9:06 |
| | | 14MAY2020 21:40 | Nausea | Mild | 6 | | 08MAY2020 9:06 |
| | | 14MAY2020 21:40 | Diarrhea | Mild | 6 | | 08MAY2020 9:06 |
| | | 14MAY2020 21:40 | Headache | Moderate | 6 | | 08MAY2020 9:06 |
| | | 14MAY2020 21:40 | Fatigue | Mild | 6 | | 08MAY2020 9:06 |
| | | 29MAY2020 22:12 | Nausea | Moderate | 21 | 0 | 08MAY2020 9:06 |
| | | 29MAY2020 22:12 | Headache | Moderate | 21 | 0 | 08MAY2020 9:06 |
| | | 29MAY2020 22:12 | Fatigue | Moderate | 21 | 0 | 08MAY2020 9:06 |
| | | 29MAY2020 22:12 | Myalgia | Moderate | 21 | 0 | 08MAY2020 9:06 |
| | | 29MAY2020 22:12 | Loss of Appetite | Moderate | 21 | 0 | 08MAY2020 9:06 |
| | | 29MAY2020 22:12 | Malaise | Mild | 21 | 0 | 08MAY2020 9:06 |
| | | 30MAY2020 21:19 | Nausea | Moderate | 22 | 1 | 08MAY2020 9:06 |
| | | 30MAY2020 21:19 | Headache | Moderate | 22 | 1 | 08MAY2020 9:06 |
| | | 30MAY2020 21:19 | Myalgia | Moderate | 22 | 1 | 08MAY2020 9:06 |
| | | 30MAY2020 21:19 | Chills | Mild | 22 | 1 | 08MAY2020 9:06 |
| | | 30MAY2020 21:19 | Loss of Appetite | Moderate | 22 | 1 | 08MAY2020 9:06 |
| | | 30MAY2020 21:19 | Malaise | Moderate | 22 | 1 | 08MAY2020 9:06 |
| 31MAY2020 21:05 | Headache | Mild | 23 | 2 | 08MAY2020 9:06 | | |
| Program: Lsaf_sysR_1.sas (Page 5 of 92) | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---|-----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 1 µg Younger | 10041 | 31MAY2020 21:05 | Fatigue | Mild | 23 | 2 | 08MAY2020 9:06 |
| | | 31MAY2020 21:05 | Loss of Appetite | Severe | 23 | 2 | 08MAY2020 9:06 |
| | | 31MAY2020 21:05 | Malaise | Moderate | 23 | 2 | 08MAY2020 9:06 |
| | | 01JUN2020 21:14 | Loss of Appetite | Severe | 24 | 3 | 08MAY2020 9:06 |
| | | 01JUN2020 21:14 | Malaise | Moderate | 24 | 3 | 08MAY2020 9:06 |
| | | 02JUN2020 21:32 | Nausea | Moderate | 25 | 4 | 08MAY2020 9:06 |
| | | 02JUN2020 21:32 | Loss of Appetite | Moderate | 25 | 4 | 08MAY2020 9:06 |
| | | 02JUN2020 21:32 | Malaise | Moderate | 25 | 4 | 08MAY2020 9:06 |
| | | 03JUN2020 21:36 | Loss of Appetite | Moderate | 26 | 5 | 08MAY2020 9:06 |
| | 03JUN2020 21:36 | Malaise | Moderate | 26 | 5 | 08MAY2020 9:06 | |
| | 10042 | 08MAY2020 22:00 | Fatigue | Mild | 0 | | 08MAY2020 9:22 |
| | 10045 | 05MAY2020 20:30 | Fatigue | Mild | 0 | | 05MAY2020 10:33 |
| | 10048 | 08MAY2020 20:06 | Fatigue | Mild | 0 | | 08MAY2020 9:36 |
| | 10052 | 08MAY2020 23:00 | Headache | Mild | 0 | | 08MAY2020 9:51 |
| 13MAY2020 23:40 | | Headache | Moderate | 5 | | 08MAY2020 9:51 | |
| 30MAY2020 23:44 | | Fatigue | Moderate | 22 | 1 | 08MAY2020 9:51 | |
| 02JUN2020 | | Headache | Moderate | 25 | 4 | 08MAY2020 9:51 | |
| 3 µg Younger | 10170 | 31JUL2020 20:00 | Fatigue | Moderate | 0 | | 31JUL2020 8:00 |
| Program: Lsaf_sysR_1.sas (Page 6 of 92) | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|-----------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|----------------|
| 3 µg Younger | 10170 | 01AUG2020 20:05 | Fatigue | Mild | 1 | | 31JUL2020 8:00 | |
| | | 21AUG2020 20:04 | Headache | Mild | 21 | 0 | 31JUL2020 8:00 | |
| | | 21AUG2020 20:04 | Fatigue | Mild | 21 | 0 | 31JUL2020 8:00 | |
| | 10194 | 22JUL2020 21:15 | Headache | Mild | 0 | | | 22JUL2020 8:00 |
| | | 22JUL2020 21:15 | Fatigue | Mild | 0 | | | 22JUL2020 8:00 |
| | | 12AUG2020 22:15 | Headache | Moderate | 21 | 0 | | 22JUL2020 8:00 |
| | | 12AUG2020 22:15 | Fatigue | Mild | 21 | 0 | | 22JUL2020 8:00 |
| | | 12AUG2020 22:15 | Malaise | Moderate | 21 | 0 | | 22JUL2020 8:00 |
| | | 13AUG2020 21:45 | Headache | Mild | 22 | 1 | | 22JUL2020 8:00 |
| | | 13AUG2020 21:45 | Fatigue | Mild | 22 | 1 | | 22JUL2020 8:00 |
| | | 13AUG2020 21:45 | Myalgia | Mild | 22 | 1 | | 22JUL2020 8:00 |
| | | 13AUG2020 21:45 | Malaise | Mild | 22 | 1 | | 22JUL2020 8:00 |
| | | 17AUG2020 22:00 | Headache | Mild | 26 | 5 | | 22JUL2020 8:00 |
| | | 17AUG2020 22:00 | Malaise | Mild | 26 | 5 | | 22JUL2020 8:00 |
| | 10204 | 25JUL2020 23:15 | Headache | Mild | 3 | | | 22JUL2020 8:45 |
| | 10212 | 23JUL2020 21:30 | Fatigue | Mild | 1 | | | 22JUL2020 9:15 |
| | | 24JUL2020 20:30 | Diarrhea | Mild | 2 | | | 22JUL2020 9:15 |
| 24JUL2020 20:30 | | Fatigue | Mild | 2 | | | 22JUL2020 9:15 | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|--------------|---|-------------------------|-------------------|---------------------|---|---|---------------------------------|----------------|
| 3 µg Younger | 10212 | 12AUG2020 21:30 | Fatigue | Mild | 21 | 0 | 22JUL2020 9:15 | |
| | | 13AUG2020 20:00 | Nausea | Mild | 22 | 1 | 22JUL2020 9:15 | |
| | | 13AUG2020 20:00 | Headache | Moderate | 22 | 1 | 22JUL2020 9:15 | |
| | | 13AUG2020 20:00 | Fatigue | Moderate | 22 | 1 | 22JUL2020 9:15 | |
| | | 13AUG2020 20:00 | Arthralgia | Moderate | 22 | 1 | 22JUL2020 9:15 | |
| | | 13AUG2020 20:00 | Loss of Appetite | Mild | 22 | 1 | 22JUL2020 9:15 | |
| | | 13AUG2020 20:00 | Malaise | Moderate | 22 | 1 | 22JUL2020 9:15 | |
| | | 13AUG2020 20:00 | Fever | Moderate | 22 | 1 | 22JUL2020 9:15 | |
| | | 14AUG2020 20:00 | Fatigue | Mild | 23 | 2 | 22JUL2020 9:15 | |
| | | 14AUG2020 20:00 | Malaise | Mild | 23 | 2 | 22JUL2020 9:15 | |
| | 10221 | 31JUL2020 20:00 | Headache | Mild | 0 | | | 31JUL2020 9:00 |
| | | 31JUL2020 20:00 | Fatigue | Moderate | 0 | | | 31JUL2020 9:00 |
| | | 02AUG2020 20:00 | Fatigue | Mild | 2 | | | 31JUL2020 9:00 |
| | | 21AUG2020 20:00 | Fatigue | Mild | 21 | 0 | | 31JUL2020 9:00 |
| | 10224 | 23AUG2020 20:00 | Headache | Moderate | 23 | 2 | | 31JUL2020 8:15 |
| | | 23AUG2020 20:00 | Fatigue | Moderate | 23 | 2 | | 31JUL2020 8:15 |
| | | 25AUG2020 19:00 | Headache | Mild | 25 | 4 | | 31JUL2020 8:15 |
| | | 25AUG2020 19:00 | Fatigue | Mild | 25 | 4 | | 31JUL2020 8:15 |
| | Program: Lsaf_sysR_1.sas (Page 8 of 92) | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 3 µg Younger | 10224 | 26AUG2020 20:00 | Fatigue | Mild | 26 | 5 | 31JUL2020 8:15 |
| | 10225 | 31JUL2020 20:15 | Headache | Mild | 0 | | 31JUL2020 8:30 |
| | | 31JUL2020 20:15 | Fatigue | Moderate | 0 | | 31JUL2020 8:30 |
| | 10226 | 31JUL2020 20:00 | Headache | Mild | 0 | | 31JUL2020 8:45 |
| | | 31JUL2020 20:00 | Fatigue | Moderate | 0 | | 31JUL2020 8:45 |
| | | 01AUG2020 20:00 | Headache | Mild | 1 | | 31JUL2020 8:45 |
| | | 01AUG2020 20:00 | Fatigue | Mild | 1 | | 31JUL2020 8:45 |
| | | 01AUG2020 20:00 | Chills | Mild | 1 | | 31JUL2020 8:45 |
| | | 02AUG2020 20:00 | Headache | Mild | 2 | | 31JUL2020 8:45 |
| | | 02AUG2020 20:00 | Fatigue | Mild | 2 | | 31JUL2020 8:45 |
| | | 02AUG2020 20:00 | Chills | Mild | 2 | | 31JUL2020 8:45 |
| | | 03AUG2020 20:00 | Headache | Mild | 3 | | 31JUL2020 8:45 |
| | | 03AUG2020 20:00 | Fatigue | Mild | 3 | | 31JUL2020 8:45 |
| | | 03AUG2020 20:00 | Chills | Mild | 3 | | 31JUL2020 8:45 |
| | | 04AUG2020 20:00 | Chills | Mild | 4 | | 31JUL2020 8:45 |
| | | 05AUG2020 20:00 | Chills | Mild | 5 | | 31JUL2020 8:45 |
| | | 06AUG2020 20:00 | Chills | Mild | 6 | | 31JUL2020 8:45 |
| 07AUG2020 8:11 | | Chills | Mild | 7 | | 31JUL2020 8:45 | |
| Program: Lsaf_sysR_1.sas (Page 9 of 92) | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 3 µg Younger | 10226 | 21AUG2020 20:00 | Headache | Mild | 21 | 0 | 31JUL2020 8:45 |
| | | 21AUG2020 20:00 | Fatigue | Severe | 21 | 0 | 31JUL2020 8:45 |
| | | 21AUG2020 20:00 | Myalgia | Mild | 21 | 0 | 31JUL2020 8:45 |
| | | 22AUG2020 20:00 | Headache | Moderate | 22 | 1 | 31JUL2020 8:45 |
| | | 22AUG2020 20:00 | Fatigue | Moderate | 22 | 1 | 31JUL2020 8:45 |
| | | 22AUG2020 20:00 | Myalgia | Mild | 22 | 1 | 31JUL2020 8:45 |
| | | 23AUG2020 20:00 | Headache | Moderate | 23 | 2 | 31JUL2020 8:45 |
| | | 23AUG2020 20:00 | Fatigue | Moderate | 23 | 2 | 31JUL2020 8:45 |
| | | 23AUG2020 20:00 | Myalgia | Mild | 23 | 2 | 31JUL2020 8:45 |
| | | 23AUG2020 20:00 | Chills | Mild | 23 | 2 | 31JUL2020 8:45 |
| | | 24AUG2020 20:00 | Headache | Mild | 24 | 3 | 31JUL2020 8:45 |
| | | 24AUG2020 20:00 | Fatigue | Mild | 24 | 3 | 31JUL2020 8:45 |
| | | 24AUG2020 20:00 | Myalgia | Mild | 24 | 3 | 31JUL2020 8:45 |
| | | 24AUG2020 20:00 | Chills | Mild | 24 | 3 | 31JUL2020 8:45 |
| | | 25AUG2020 20:00 | Fatigue | Mild | 25 | 4 | 31JUL2020 8:45 |
| | | 25AUG2020 20:00 | Myalgia | Mild | 25 | 4 | 31JUL2020 8:45 |
| | | 26AUG2020 20:00 | Fatigue | Mild | 26 | 5 | 31JUL2020 8:45 |
| | | 10227 | 06AUG2020 18:00 | Headache | Mild | 6 | |
| Program: Lsaf_sysR_1.sas (Page 10 of 92) | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 3 µg Younger | 10227 | 21AUG2020 | Headache | Moderate | 21 | 0 | 31JUL2020 9:15 |
| 10 µg Younger | 10003 | 19MAY2020 20:35 | Headache | Mild | 21 | 0 | 28APR2020 8:30 |
| | 10004 | 25APR2020 21:00 | Diarrhea | Mild | 1 | | 24APR2020 9:15 |
| | | 26APR2020 21:30 | Diarrhea | Mild | 2 | | 24APR2020 9:15 |
| | | 15MAY2020 21:30 | Nausea | Moderate | 21 | 0 | 24APR2020 9:15 |
| | | 15MAY2020 21:30 | Headache | Moderate | 21 | 0 | 24APR2020 9:15 |
| | | 15MAY2020 21:30 | Fatigue | Mild | 21 | 0 | 24APR2020 9:15 |
| | | 15MAY2020 21:30 | Arthralgia | Mild | 21 | 0 | 24APR2020 9:15 |
| | | 15MAY2020 21:30 | Chills | Severe | 21 | 0 | 24APR2020 9:15 |
| | | 16MAY2020 22:15 | Headache | Mild | 22 | 1 | 24APR2020 9:15 |
| | | 16MAY2020 22:15 | Fatigue | Mild | 22 | 1 | 24APR2020 9:15 |
| | | 16MAY2020 22:15 | Myalgia | Mild | 22 | 1 | 24APR2020 9:15 |
| | | 16MAY2020 22:15 | Arthralgia | Mild | 22 | 1 | 24APR2020 9:15 |
| | | 16MAY2020 22:15 | Chills | Mild | 22 | 1 | 24APR2020 9:15 |
| | | 16MAY2020 22:15 | Loss of Appetite | Mild | 22 | 1 | 24APR2020 9:15 |
| | | 16MAY2020 22:15 | Malaise | Mild | 22 | 1 | 24APR2020 9:15 |
| | | 17MAY2020 23:15 | Fatigue | Mild | 23 | 2 | 24APR2020 9:15 |
| 17MAY2020 23:15 | Myalgia | Mild | 23 | 2 | 24APR2020 9:15 | | |
| Program: Lsaf_sysR_1.sas (Page 11 of 92) | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 10 µg Younger | 10004 | 17MAY2020 23:15 | Arthralgia | Mild | 23 | 2 | 24APR2020 9:15 |
| | 10005 | 24APR2020 13:00 | Headache | Moderate | 0 | | 24APR2020 11:15 |
| | | 24APR2020 13:00 | Fatigue | Moderate | 0 | | 24APR2020 11:15 |
| | | 25APR2020 19:30 | Headache | Mild | 1 | | 24APR2020 11:15 |
| | | 25APR2020 19:30 | Fatigue | Mild | 1 | | 24APR2020 11:15 |
| | | 28APR2020 19:45 | Fatigue | Mild | 4 | | 24APR2020 11:15 |
| | | 15MAY2020 19:00 | Headache | Mild | 21 | 0 | 24APR2020 11:15 |
| | | 15MAY2020 19:00 | Fatigue | Moderate | 21 | 0 | 24APR2020 11:15 |
| | | 15MAY2020 19:00 | Myalgia | Mild | 21 | 0 | 24APR2020 11:15 |
| | | 15MAY2020 19:00 | Chills | Moderate | 21 | 0 | 24APR2020 11:15 |
| | | 16MAY2020 19:00 | Fatigue | Moderate | 22 | 1 | 24APR2020 11:15 |
| | | 16MAY2020 19:00 | Myalgia | Moderate | 22 | 1 | 24APR2020 11:15 |
| | | 16MAY2020 19:00 | Arthralgia | Moderate | 22 | 1 | 24APR2020 11:15 |
| | | 16MAY2020 19:00 | Chills | Moderate | 22 | 1 | 24APR2020 11:15 |
| | | 16MAY2020 19:00 | Loss of Appetite | Moderate | 22 | 1 | 24APR2020 11:15 |
| | | 16MAY2020 19:00 | Malaise | Moderate | 22 | 1 | 24APR2020 11:15 |
| | | 17MAY2020 19:00 | Headache | Moderate | 23 | 2 | 24APR2020 11:15 |
| | | 17MAY2020 19:00 | Fatigue | Moderate | 23 | 2 | 24APR2020 11:15 |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|--|-------------------|---------------------|---|---|---------------------------------|
| 10 µg Younger | 10005 | 18MAY2020 19:00 | Fatigue | Mild | 24 | 3 | 24APR2020 11:15 |
| | | 19MAY2020 19:00 | Fatigue | Moderate | 25 | 4 | 24APR2020 11:15 |
| | | 19MAY2020 19:00 | Malaise | Mild | 25 | 4 | 24APR2020 11:15 |
| | | 20MAY2020 19:00 | Fatigue | Moderate | 26 | 5 | 24APR2020 11:15 |
| | | 21MAY2020 19:00 | Fatigue | Moderate | 27 | 6 | 24APR2020 11:15 |
| | | 21MAY2020 19:00 | Malaise | Mild | 27 | 6 | 24APR2020 11:15 |
| | | 22MAY2020 19:00 | Fatigue | Moderate | 28 | 7 | 24APR2020 11:15 |
| | 10006 | 29APR2020 22:00 | Headache | Mild | 1 | | 28APR2020 9:00 |
| | | 29APR2020 22:00 | Fatigue | Mild | 1 | | 28APR2020 9:00 |
| | | 19MAY2020 22:00 | Fatigue | Mild | 21 | 0 | 28APR2020 9:00 |
| | | 19MAY2020 22:00 | Chills | Mild | 21 | 0 | 28APR2020 9:00 |
| | | 19MAY2020 22:00 | Fever | Severe | 21 | 0 | 28APR2020 9:00 |
| | | 20MAY2020 22:00 | Nausea | Mild | 22 | 1 | 28APR2020 9:00 |
| | | 20MAY2020 22:00 | Fatigue | Moderate | 22 | 1 | 28APR2020 9:00 |
| | | 20MAY2020 22:00 | Myalgia | Mild | 22 | 1 | 28APR2020 9:00 |
| | | 20MAY2020 22:00 | Chills | Mild | 22 | 1 | 28APR2020 9:00 |
| | | 20MAY2020 22:00 | Malaise | Mild | 22 | 1 | 28APR2020 9:00 |
| | | 20MAY2020 22:00 | Fever | Mild | 22 | 1 | 28APR2020 9:00 |
| | | Program: Lsaf_sysR_1.sas (Page 13 of 92) | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 10 µg Younger | 10007 | | Headache | Moderate | | | 23APR2020 11:08 |
| | | | Loss of Appetite | Mild | | | 23APR2020 11:08 |
| | | | Malaise | Mild | | | 23APR2020 11:08 |
| | | 23APR2020 20:00 | Headache | Moderate | 0 | | 23APR2020 11:08 |
| | | 24APR2020 9:00 | Headache | Mild | 1 | | 23APR2020 11:08 |
| | | 24APR2020 9:00 | Myalgia | Mild | 1 | | 23APR2020 11:08 |
| | | 25APR2020 9:00 | Headache | Mild | 2 | | 23APR2020 11:08 |
| | | 25APR2020 9:00 | Fatigue | Mild | 2 | | 23APR2020 11:08 |
| | | 26APR2020 8:00 | Headache | Moderate | 3 | | 23APR2020 11:08 |
| | | 26APR2020 8:00 | Fatigue | Mild | 3 | | 23APR2020 11:08 |
| | | 27APR2020 9:00 | Headache | Moderate | 4 | | 23APR2020 11:08 |
| | | 27APR2020 9:00 | Fatigue | Mild | 4 | | 23APR2020 11:08 |
| | | 28APR2020 9:00 | Headache | Mild | 5 | | 23APR2020 11:08 |
| | | 14MAY2020 | Headache | Mild | 21 | 0 | 23APR2020 11:08 |
| | | 14MAY2020 | Fatigue | Mild | 21 | 0 | 23APR2020 11:08 |
| | | 14MAY2020 | Myalgia | Moderate | 21 | 0 | 23APR2020 11:08 |
| | | 14MAY2020 | Malaise | Mild | 21 | 0 | 23APR2020 11:08 |
| 15MAY2020 20:00 | Headache | Moderate | 22 | 1 | 23APR2020 11:08 | | |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-----------------|-----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 10 µg Younger | 10007 | 15MAY2020 20:00 | Fatigue | Moderate | 22 | 1 | 23APR2020 11:08 |
| | | 15MAY2020 20:00 | Myalgia | Mild | 22 | 1 | 23APR2020 11:08 |
| | | 15MAY2020 20:00 | Malaise | Mild | 22 | 1 | 23APR2020 11:08 |
| | | 16MAY2020 20:00 | Headache | Mild | 23 | 2 | 23APR2020 11:08 |
| | | 16MAY2020 20:00 | Fatigue | Mild | 23 | 2 | 23APR2020 11:08 |
| | | 16MAY2020 20:00 | Myalgia | Mild | 23 | 2 | 23APR2020 11:08 |
| | | 16MAY2020 20:00 | Malaise | Mild | 23 | 2 | 23APR2020 11:08 |
| | | 17MAY2020 20:00 | Headache | Mild | 24 | 3 | 23APR2020 11:08 |
| | | 17MAY2020 20:00 | Myalgia | Mild | 24 | 3 | 23APR2020 11:08 |
| | | 18MAY2020 20:00 | Headache | Mild | 25 | 4 | 23APR2020 11:08 |
| | 18MAY2020 20:00 | Myalgia | Mild | 25 | 4 | 23APR2020 11:08 | |
| | 10008 | 28APR2020 22:00 | Fatigue | Mild | 0 | | 28APR2020 9:30 |
| | | 19MAY2020 22:00 | Nausea | Severe | 21 | 0 | 28APR2020 9:30 |
| | | 19MAY2020 22:00 | Headache | Mild | 21 | 0 | 28APR2020 9:30 |
| | | 19MAY2020 22:00 | Fatigue | Moderate | 21 | 0 | 28APR2020 9:30 |
| | | 19MAY2020 22:00 | Chills | Severe | 21 | 0 | 28APR2020 9:30 |
| | | 19MAY2020 22:00 | Loss of Appetite | Severe | 21 | 0 | 28APR2020 9:30 |
| 19MAY2020 22:00 | | Malaise | Severe | 21 | 0 | 28APR2020 9:30 | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|--|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 10 µg Younger | 10008 | 19MAY2020 22:00 | Fever | Mild | 21 | 0 | 28APR2020 9:30 |
| | | 20MAY2020 22:00 | Nausea | Mild | 22 | 1 | 28APR2020 9:30 |
| | | 20MAY2020 22:00 | Fatigue | Mild | 22 | 1 | 28APR2020 9:30 |
| | | 20MAY2020 22:00 | Chills | Mild | 22 | 1 | 28APR2020 9:30 |
| | | 20MAY2020 22:00 | Loss of Appetite | Mild | 22 | 1 | 28APR2020 9:30 |
| | | 20MAY2020 22:00 | Malaise | Mild | 22 | 1 | 28APR2020 9:30 |
| | 10009 | 28APR2020 21:00 | Fatigue | Mild | 0 | | 28APR2020 10:00 |
| | | 19MAY2020 22:00 | Headache | Mild | 21 | 0 | 28APR2020 10:00 |
| | | 19MAY2020 22:00 | Fatigue | Mild | 21 | 0 | 28APR2020 10:00 |
| | | 19MAY2020 22:00 | Myalgia | Mild | 21 | 0 | 28APR2020 10:00 |
| | | 20MAY2020 19:00 | Headache | Mild | 22 | 1 | 28APR2020 10:00 |
| | | 20MAY2020 19:00 | Fatigue | Mild | 22 | 1 | 28APR2020 10:00 |
| | | 20MAY2020 19:00 | Myalgia | Mild | 22 | 1 | 28APR2020 10:00 |
| | | 20MAY2020 19:00 | Chills | Mild | 22 | 1 | 28APR2020 10:00 |
| | 10010 | 24APR2020 18:15 | Fatigue | Mild | 0 | | 24APR2020 12:15 |
| | | 25APR2020 18:15 | Nausea | Severe | 1 | | 24APR2020 12:15 |
| | | 25APR2020 18:15 | Headache | Severe | 1 | | 24APR2020 12:15 |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 10 µg Younger | 10010 | 25APR2020 18:15 | Fatigue | Severe | 1 | | 24APR2020 12:15 |
| | | 25APR2020 18:15 | Myalgia | Moderate | 1 | | 24APR2020 12:15 |
| | | 25APR2020 18:15 | Arthralgia | Moderate | 1 | | 24APR2020 12:15 |
| | | 25APR2020 18:15 | Chills | Severe | 1 | | 24APR2020 12:15 |
| | | 25APR2020 18:15 | Loss of Appetite | Mild | 1 | | 24APR2020 12:15 |
| | | 25APR2020 18:15 | Malaise | Moderate | 1 | | 24APR2020 12:15 |
| | | 26APR2020 18:15 | Nausea | Moderate | 2 | | 24APR2020 12:15 |
| | | 26APR2020 18:15 | Diarrhea | Moderate | 2 | | 24APR2020 12:15 |
| | | 26APR2020 18:15 | Headache | Severe | 2 | | 24APR2020 12:15 |
| | | 26APR2020 18:15 | Fatigue | Moderate | 2 | | 24APR2020 12:15 |
| | | 26APR2020 18:15 | Myalgia | Moderate | 2 | | 24APR2020 12:15 |
| | | 26APR2020 18:15 | Arthralgia | Moderate | 2 | | 24APR2020 12:15 |
| | | 26APR2020 18:15 | Chills | Mild | 2 | | 24APR2020 12:15 |
| | | 26APR2020 18:15 | Loss of Appetite | Mild | 2 | | 24APR2020 12:15 |
| | | 26APR2020 18:15 | Malaise | Mild | 2 | | 24APR2020 12:15 |
| | | 27APR2020 18:15 | Nausea | Moderate | 3 | | 24APR2020 12:15 |
| | | 27APR2020 18:15 | Diarrhea | Mild | 3 | | 24APR2020 12:15 |
| | | 27APR2020 18:15 | Headache | Moderate | 3 | | 24APR2020 12:15 |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 10 µg Younger | 10010 | 27APR2020 18:15 | Fatigue | Moderate | 3 | | 24APR2020 12:15 |
| | | 27APR2020 18:15 | Myalgia | Moderate | 3 | | 24APR2020 12:15 |
| | | 27APR2020 18:15 | Arthralgia | Mild | 3 | | 24APR2020 12:15 |
| | | 27APR2020 18:15 | Loss of Appetite | Mild | 3 | | 24APR2020 12:15 |
| | | 27APR2020 18:15 | Malaise | Mild | 3 | | 24APR2020 12:15 |
| | | 28APR2020 18:30 | Nausea | Mild | 4 | | 24APR2020 12:15 |
| | | 28APR2020 18:30 | Headache | Moderate | 4 | | 24APR2020 12:15 |
| | | 28APR2020 18:30 | Fatigue | Moderate | 4 | | 24APR2020 12:15 |
| | | 28APR2020 18:30 | Myalgia | Moderate | 4 | | 24APR2020 12:15 |
| | | 28APR2020 18:30 | Arthralgia | Mild | 4 | | 24APR2020 12:15 |
| | | 28APR2020 18:30 | Malaise | Mild | 4 | | 24APR2020 12:15 |
| | | 29APR2020 18:30 | Headache | Moderate | 5 | | 24APR2020 12:15 |
| | | 29APR2020 18:30 | Fatigue | Moderate | 5 | | 24APR2020 12:15 |
| | | 29APR2020 18:30 | Myalgia | Moderate | 5 | | 24APR2020 12:15 |
| | | 29APR2020 18:30 | Arthralgia | Mild | 5 | | 24APR2020 12:15 |
| | | 29APR2020 18:30 | Malaise | Mild | 5 | | 24APR2020 12:15 |
| | | 30APR2020 18:15 | Headache | Mild | 6 | | 24APR2020 12:15 |
| | | 30APR2020 18:15 | Fatigue | Moderate | 6 | | 24APR2020 12:15 |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|-----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 10 µg Younger | 10010 | 30APR2020 18:15 | Myalgia | Mild | 6 | | 24APR2020 12:15 |
| | | 30APR2020 18:15 | Malaise | Mild | 6 | | 24APR2020 12:15 |
| | | 01MAY2020 18:45 | Nausea | Mild | 7 | | 24APR2020 12:15 |
| | | 01MAY2020 18:45 | Diarrhea | Mild | 7 | | 24APR2020 12:15 |
| | | 01MAY2020 18:45 | Headache | Moderate | 7 | | 24APR2020 12:15 |
| | | 01MAY2020 18:45 | Fatigue | Moderate | 7 | | 24APR2020 12:15 |
| | | 01MAY2020 18:45 | Myalgia | Moderate | 7 | | 24APR2020 12:15 |
| | | 01MAY2020 18:45 | Chills | Mild | 7 | | 24APR2020 12:15 |
| | | 01MAY2020 18:45 | Loss of Appetite | Mild | 7 | | 24APR2020 12:15 |
| | | 01MAY2020 18:45 | Malaise | Mild | 7 | | 24APR2020 12:15 |
| | | 02MAY2020 19:00 | Headache | Mild | 8 | | 24APR2020 12:15 |
| | | 02MAY2020 19:00 | Fatigue | Moderate | 8 | | 24APR2020 12:15 |
| | | 02MAY2020 19:00 | Myalgia | Moderate | 8 | | 24APR2020 12:15 |
| | | 02MAY2020 19:00 | Malaise | Mild | 8 | | 24APR2020 12:15 |
| | 10017 | 28APR2020 22:00 | Headache | Mild | 0 | | 28APR2020 10:30 |
| | | 19MAY2020 22:00 | Headache | Mild | 21 | 0 | 28APR2020 10:30 |
| | 19MAY2020 22:00 | Fever | Moderate | 21 | 0 | 28APR2020 10:30 | |
| | 20MAY2020 21:47 | Headache | Mild | 22 | 1 | 28APR2020 10:30 | |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 10 µg Younger | 10017 | 20MAY2020 21:47 | Myalgia | Severe | 22 | 1 | 28APR2020 10:30 |
| | | 21MAY2020 21:39 | Myalgia | Mild | 23 | 2 | 28APR2020 10:30 |
| | 10019 | 20MAY2020 18:10 | Headache | Severe | 22 | 1 | 28APR2020 11:00 |
| | | 20MAY2020 18:10 | Arthralgia | Mild | 22 | 1 | 28APR2020 11:00 |
| | | 20MAY2020 18:10 | Loss of Appetite | Mild | 22 | 1 | 28APR2020 11:00 |
| | | 20MAY2020 18:10 | Malaise | Mild | 22 | 1 | 28APR2020 11:00 |
| | | 20MAY2020 18:10 | Fever | Mild | 22 | 1 | 28APR2020 11:00 |
| | | 21MAY2020 20:00 | Headache | Mild | 23 | 2 | 28APR2020 11:00 |
| | | 24MAY2020 19:20 | Headache | Mild | 26 | 5 | 28APR2020 11:00 |
| | | 25MAY2020 19:55 | Headache | Mild | 27 | 6 | 28APR2020 11:00 |
| | | 26MAY2020 18:45 | Headache | Mild | 28 | 7 | 28APR2020 11:00 |
| | | 27MAY2020 7:10 | Headache | Mild | 29 | 8 | 28APR2020 11:00 |
| 20 µg Younger | 10151 | 16JUL2020 18:00 | Fatigue | Mild | 0 | | 16JUL2020 8:00 |
| | | 17JUL2020 20:00 | Nausea | Mild | 1 | | 16JUL2020 8:00 |
| | | 17JUL2020 20:00 | Fatigue | Mild | 1 | | 16JUL2020 8:00 |
| | | 18JUL2020 20:00 | Fatigue | Mild | 2 | | 16JUL2020 8:00 |
| | | 06AUG2020 22:00 | Fatigue | Mild | 21 | 0 | 16JUL2020 8:00 |
| | | 07AUG2020 22:00 | Headache | Mild | 22 | 1 | 16JUL2020 8:00 |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 10151 | 07AUG2020 22:00 | Fatigue | Moderate | 22 | 1 | 16JUL2020 8:00 |
| | | 08AUG2020 22:00 | Headache | Mild | 23 | 2 | 16JUL2020 8:00 |
| | | 08AUG2020 22:00 | Fatigue | Mild | 23 | 2 | 16JUL2020 8:00 |
| | | 09AUG2020 22:00 | Fatigue | Mild | 24 | 3 | 16JUL2020 8:00 |
| | | 10AUG2020 22:00 | Fatigue | Mild | 25 | 4 | 16JUL2020 8:00 |
| | | 11AUG2020 22:00 | Fatigue | Mild | 26 | 5 | 16JUL2020 8:00 |
| | 10171 | 16JUL2020 17:40 | Fatigue | Mild | 0 | | 16JUL2020 8:15 |
| | | 16JUL2020 17:40 | Chills | Mild | 0 | | 16JUL2020 8:15 |
| | | 16JUL2020 17:40 | Malaise | Mild | 0 | | 16JUL2020 8:15 |
| | | 17JUL2020 20:28 | Fatigue | Mild | 1 | | 16JUL2020 8:15 |
| | | 17JUL2020 20:28 | Chills | Mild | 1 | | 16JUL2020 8:15 |
| | | 17JUL2020 20:28 | Malaise | Mild | 1 | | 16JUL2020 8:15 |
| | | 18JUL2020 20:10 | Fatigue | Mild | 2 | | 16JUL2020 8:15 |
| | | 06AUG2020 20:22 | Headache | Moderate | 21 | 0 | 16JUL2020 8:15 |
| | | 06AUG2020 20:22 | Fatigue | Mild | 21 | 0 | 16JUL2020 8:15 |
| | | 06AUG2020 20:22 | Myalgia | Mild | 21 | 0 | 16JUL2020 8:15 |
| | | 06AUG2020 20:22 | Chills | Severe | 21 | 0 | 16JUL2020 8:15 |
| | | 06AUG2020 20:22 | Loss of Appetite | Moderate | 21 | 0 | 16JUL2020 8:15 |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 10171 | 06AUG2020 20:22 | Malaise | Moderate | 21 | 0 | 16JUL2020 8:15 |
| | | 06AUG2020 20:22 | Fever | Severe | 21 | 0 | 16JUL2020 8:15 |
| | | 07AUG2020 20:10 | Headache | Moderate | 22 | 1 | 16JUL2020 8:15 |
| | | 07AUG2020 20:10 | Fatigue | Mild | 22 | 1 | 16JUL2020 8:15 |
| | | 07AUG2020 20:10 | Myalgia | Mild | 22 | 1 | 16JUL2020 8:15 |
| | | 07AUG2020 20:10 | Chills | Moderate | 22 | 1 | 16JUL2020 8:15 |
| | | 07AUG2020 20:10 | Loss of Appetite | Moderate | 22 | 1 | 16JUL2020 8:15 |
| | | 07AUG2020 20:10 | Malaise | Moderate | 22 | 1 | 16JUL2020 8:15 |
| | | 07AUG2020 20:10 | Fever | Moderate | 22 | 1 | 16JUL2020 8:15 |
| | | 08AUG2020 20:06 | Headache | Moderate | 23 | 2 | 16JUL2020 8:15 |
| | | 08AUG2020 20:06 | Fatigue | Mild | 23 | 2 | 16JUL2020 8:15 |
| | | 08AUG2020 20:06 | Myalgia | Mild | 23 | 2 | 16JUL2020 8:15 |
| | | 08AUG2020 20:06 | Chills | Moderate | 23 | 2 | 16JUL2020 8:15 |
| | | 08AUG2020 20:06 | Loss of Appetite | Moderate | 23 | 2 | 16JUL2020 8:15 |
| | | 08AUG2020 20:06 | Malaise | Moderate | 23 | 2 | 16JUL2020 8:15 |
| | | 09AUG2020 19:40 | Headache | Mild | 24 | 3 | 16JUL2020 8:15 |
| | | 09AUG2020 19:40 | Fatigue | Mild | 24 | 3 | 16JUL2020 8:15 |
| | | 09AUG2020 19:40 | Chills | Mild | 24 | 3 | 16JUL2020 8:15 |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|--|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 10171 | 09AUG2020 19:40 | Loss of Appetite | Mild | 24 | 3 | 16JUL2020 8:15 |
| | | 09AUG2020 19:40 | Malaise | Mild | 24 | 3 | 16JUL2020 8:15 |
| | | 10AUG2020 20:13 | Headache | Mild | 25 | 4 | 16JUL2020 8:15 |
| | | 10AUG2020 20:13 | Fatigue | Mild | 25 | 4 | 16JUL2020 8:15 |
| | | 10AUG2020 20:13 | Chills | Mild | 25 | 4 | 16JUL2020 8:15 |
| | | 10AUG2020 20:13 | Loss of Appetite | Mild | 25 | 4 | 16JUL2020 8:15 |
| | | 10AUG2020 20:13 | Malaise | Mild | 25 | 4 | 16JUL2020 8:15 |
| | 10172 | 16JUL2020 20:16 | Fatigue | Mild | 0 | | 16JUL2020 8:30 |
| | | 17JUL2020 20:23 | Fatigue | Mild | 1 | | 16JUL2020 8:30 |
| | | 18JUL2020 20:41 | Fatigue | Mild | 2 | | 16JUL2020 8:30 |
| | | 19JUL2020 20:16 | Fatigue | Mild | 3 | | 16JUL2020 8:30 |
| | | 20JUL2020 20:20 | Fatigue | Mild | 4 | | 16JUL2020 8:30 |
| | | 21JUL2020 20:15 | Fatigue | Mild | 5 | | 16JUL2020 8:30 |
| | | 06AUG2020 19:50 | Headache | Moderate | 21 | 0 | 16JUL2020 8:30 |
| | 07AUG2020 22:00 | Headache | Moderate | 22 | 1 | 16JUL2020 8:30 | |
| | 10173 | 17JUL2020 16:00 | Headache | Severe | 1 | | 16JUL2020 8:45 |
| | | 17JUL2020 16:00 | Fatigue | Moderate | 1 | | 16JUL2020 8:45 |
| | | 17JUL2020 16:00 | Myalgia | Mild | 1 | | 16JUL2020 8:45 |
| | Program: Lsaf_sysR_1.sas (Page 23 of 92) | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|--|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 10173 | 17JUL2020 16:00 | Arthralgia | Mild | 1 | | 16JUL2020 8:45 |
| | | 06AUG2020 22:00 | Headache | Moderate | 21 | 0 | 16JUL2020 8:45 |
| | | 07AUG2020 4:38 | Headache | Severe | 22 | 1 | 16JUL2020 8:45 |
| | | 07AUG2020 4:38 | Myalgia | Mild | 22 | 1 | 16JUL2020 8:45 |
| | | 07AUG2020 4:38 | Chills | Severe | 22 | 1 | 16JUL2020 8:45 |
| | | 07AUG2020 4:38 | Loss of Appetite | Moderate | 22 | 1 | 16JUL2020 8:45 |
| | | 07AUG2020 4:38 | Malaise | Moderate | 22 | 1 | 16JUL2020 8:45 |
| | | 07AUG2020 4:38 | Fever | Severe | 22 | 1 | 16JUL2020 8:45 |
| | | 08AUG2020 11:00 | Headache | Moderate | 23 | 2 | 16JUL2020 8:45 |
| | | 08AUG2020 11:00 | Fatigue | Mild | 23 | 2 | 16JUL2020 8:45 |
| | | 08AUG2020 11:00 | Loss of Appetite | Mild | 23 | 2 | 16JUL2020 8:45 |
| | | 08AUG2020 11:00 | Malaise | Mild | 23 | 2 | 16JUL2020 8:45 |
| | | 09AUG2020 13:00 | Headache | Mild | 24 | 3 | 16JUL2020 8:45 |
| | | 10175 | 16JUL2020 18:00 | Fatigue | Mild | 0 | |
| | 16JUL2020 18:00 | | Myalgia | Mild | 0 | | 16JUL2020 9:00 |
| | 17JUL2020 18:04 | | Fatigue | Mild | 1 | | 16JUL2020 9:00 |
| | 07AUG2020 21:08 | | Malaise | Mild | 22 | 1 | 16JUL2020 9:00 |
| | 08AUG2020 21:01 | | Malaise | Mild | 23 | 2 | 16JUL2020 9:00 |
| | Program: Lsaf_sysR_1.sas (Page 24 of 92) | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-----------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 10176 | 16JUL2020 21:00 | Headache | Mild | 0 | | 16JUL2020 9:15 |
| | | 16JUL2020 21:00 | Myalgia | Mild | 0 | | 16JUL2020 9:15 |
| | | 16JUL2020 21:00 | Malaise | Mild | 0 | | 16JUL2020 9:15 |
| | | 17JUL2020 20:30 | Headache | Mild | 1 | | 16JUL2020 9:15 |
| | | 17JUL2020 20:30 | Myalgia | Mild | 1 | | 16JUL2020 9:15 |
| | | 17JUL2020 20:30 | Arthralgia | Mild | 1 | | 16JUL2020 9:15 |
| | | 22JUL2020 21:00 | Fatigue | Mild | 6 | | 16JUL2020 9:15 |
| | | 06AUG2020 22:00 | Headache | Moderate | 21 | 0 | 16JUL2020 9:15 |
| | | 06AUG2020 22:00 | Myalgia | Mild | 21 | 0 | 16JUL2020 9:15 |
| | | 06AUG2020 22:00 | Chills | Mild | 21 | 0 | 16JUL2020 9:15 |
| | | 06AUG2020 22:00 | Fever | Moderate | 21 | 0 | 16JUL2020 9:15 |
| | | 07AUG2020 17:00 | Headache | Mild | 22 | 1 | 16JUL2020 9:15 |
| | | 07AUG2020 17:00 | Myalgia | Moderate | 22 | 1 | 16JUL2020 9:15 |
| | | 08AUG2020 21:00 | Myalgia | Mild | 23 | 2 | 16JUL2020 9:15 |
| | 10178 | 16JUL2020 20:15 | Nausea | Mild | 0 | | 16JUL2020 9:30 |
| | | 16JUL2020 20:15 | Headache | Moderate | 0 | | 16JUL2020 9:30 |
| 16JUL2020 20:15 | | Fatigue | Mild | 0 | | 16JUL2020 9:30 | |
| 16JUL2020 20:15 | | Chills | Mild | 0 | | 16JUL2020 9:30 | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|-----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 10178 | 16JUL2020 20:15 | Loss of Appetite | Mild | 0 | | 16JUL2020 9:30 |
| | | 16JUL2020 20:15 | Malaise | Mild | 0 | | 16JUL2020 9:30 |
| | | 17JUL2020 20:00 | Headache | Mild | 1 | | 16JUL2020 9:30 |
| | | 17JUL2020 20:00 | Fatigue | Mild | 1 | | 16JUL2020 9:30 |
| | | 17JUL2020 20:00 | Malaise | Mild | 1 | | 16JUL2020 9:30 |
| | | 21JUL2020 19:50 | Headache | Mild | 5 | | 16JUL2020 9:30 |
| | | 21JUL2020 19:50 | Fatigue | Mild | 5 | | 16JUL2020 9:30 |
| | | 06AUG2020 19:40 | Headache | Mild | 21 | 0 | 16JUL2020 9:30 |
| | | 07AUG2020 19:00 | Headache | Mild | 22 | 1 | 16JUL2020 9:30 |
| | 11AUG2020 19:45 | Headache | Mild | 26 | 5 | 16JUL2020 9:30 | |
| | 10179 | 16JUL2020 21:00 | Headache | Mild | 0 | | 16JUL2020 9:45 |
| | | 16JUL2020 21:00 | Fatigue | Mild | 0 | | 16JUL2020 9:45 |
| | | 16JUL2020 21:00 | Myalgia | Mild | 0 | | 16JUL2020 9:45 |
| | | 06AUG2020 21:00 | Nausea | Mild | 21 | 0 | 16JUL2020 9:45 |
| | | 06AUG2020 21:00 | Headache | Severe | 21 | 0 | 16JUL2020 9:45 |
| | | 06AUG2020 21:00 | Fatigue | Mild | 21 | 0 | 16JUL2020 9:45 |
| | | 07AUG2020 21:00 | Headache | Moderate | 22 | 1 | 16JUL2020 9:45 |
| 08AUG2020 21:00 | | Headache | Moderate | 23 | 2 | 16JUL2020 9:45 | |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 10181 | 16JUL2020 20:15 | Fatigue | Mild | 0 | | 16JUL2020 10:00 |
| | | 16JUL2020 20:15 | Malaise | Mild | 0 | | 16JUL2020 10:00 |
| | 10183 | 16JUL2020 21:00 | Nausea | Moderate | 0 | | 16JUL2020 10:30 |
| | | 16JUL2020 21:00 | Headache | Severe | 0 | | 16JUL2020 10:30 |
| | | 16JUL2020 21:00 | Myalgia | Severe | 0 | | 16JUL2020 10:30 |
| | | 16JUL2020 21:00 | Chills | Moderate | 0 | | 16JUL2020 10:30 |
| | | 16JUL2020 21:00 | Loss of Appetite | Mild | 0 | | 16JUL2020 10:30 |
| | | 16JUL2020 21:00 | Malaise | Moderate | 0 | | 16JUL2020 10:30 |
| | | 17JUL2020 21:10 | Headache | Severe | 1 | | 16JUL2020 10:30 |
| | | 17JUL2020 21:10 | Fatigue | Moderate | 1 | | 16JUL2020 10:30 |
| | | 17JUL2020 21:10 | Myalgia | Severe | 1 | | 16JUL2020 10:30 |
| | | 17JUL2020 21:10 | Chills | Mild | 1 | | 16JUL2020 10:30 |
| | | 17JUL2020 21:10 | Loss of Appetite | Mild | 1 | | 16JUL2020 10:30 |
| | | 17JUL2020 21:10 | Malaise | Mild | 1 | | 16JUL2020 10:30 |
| | | 18JUL2020 21:50 | Nausea | Mild | 2 | | 16JUL2020 10:30 |
| | | 18JUL2020 21:50 | Headache | Moderate | 2 | | 16JUL2020 10:30 |
| | | 18JUL2020 21:50 | Fatigue | Mild | 2 | | 16JUL2020 10:30 |
| | | 18JUL2020 21:50 | Myalgia | Moderate | 2 | | 16JUL2020 10:30 |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 10183 | 18JUL2020 21:50 | Loss of Appetite | Mild | 2 | | 16JUL2020 10:30 |
| | | 18JUL2020 21:50 | Malaise | Mild | 2 | | 16JUL2020 10:30 |
| | | 19JUL2020 21:36 | Headache | Mild | 3 | | 16JUL2020 10:30 |
| | | 19JUL2020 21:36 | Myalgia | Mild | 3 | | 16JUL2020 10:30 |
| | | 06AUG2020 18:30 | Nausea | Mild | 21 | 0 | 16JUL2020 10:30 |
| | | 06AUG2020 18:30 | Headache | Mild | 21 | 0 | 16JUL2020 10:30 |
| | | 06AUG2020 18:30 | Fatigue | Moderate | 21 | 0 | 16JUL2020 10:30 |
| | | 06AUG2020 18:30 | Myalgia | Moderate | 21 | 0 | 16JUL2020 10:30 |
| | | 06AUG2020 18:30 | Chills | Mild | 21 | 0 | 16JUL2020 10:30 |
| | | 06AUG2020 18:30 | Loss of Appetite | Mild | 21 | 0 | 16JUL2020 10:30 |
| | | 06AUG2020 18:30 | Malaise | Mild | 21 | 0 | 16JUL2020 10:30 |
| | | 07AUG2020 20:10 | Headache | Moderate | 22 | 1 | 16JUL2020 10:30 |
| | | 07AUG2020 20:10 | Fatigue | Mild | 22 | 1 | 16JUL2020 10:30 |
| | | 07AUG2020 20:10 | Myalgia | Severe | 22 | 1 | 16JUL2020 10:30 |
| | | 07AUG2020 20:10 | Loss of Appetite | Mild | 22 | 1 | 16JUL2020 10:30 |
| | | 08AUG2020 20:30 | Headache | Mild | 23 | 2 | 16JUL2020 10:30 |
| | | 08AUG2020 20:30 | Myalgia | Moderate | 23 | 2 | 16JUL2020 10:30 |
| | | 09AUG2020 21:00 | Myalgia | Mild | 24 | 3 | 16JUL2020 10:30 |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 10197 | 16JUL2020 20:30 | Headache | Moderate | 0 | | 16JUL2020 10:45 |
| | | 16JUL2020 20:30 | Fatigue | Moderate | 0 | | 16JUL2020 10:45 |
| | | 16JUL2020 20:30 | Malaise | Mild | 0 | | 16JUL2020 10:45 |
| | | 17JUL2020 2:30 | Nausea | Mild | 1 | | 16JUL2020 10:45 |
| | | 17JUL2020 2:30 | Headache | Mild | 1 | | 16JUL2020 10:45 |
| | | 17JUL2020 2:30 | Fatigue | Moderate | 1 | | 16JUL2020 10:45 |
| | | 17JUL2020 2:30 | Myalgia | Mild | 1 | | 16JUL2020 10:45 |
| | | 17JUL2020 2:30 | Chills | Moderate | 1 | | 16JUL2020 10:45 |
| | | 17JUL2020 2:30 | Malaise | Moderate | 1 | | 16JUL2020 10:45 |
| | | 17JUL2020 20:30 | Nausea | Mild | 1 | | 16JUL2020 10:45 |
| | | 17JUL2020 20:30 | Headache | Moderate | 1 | | 16JUL2020 10:45 |
| | | 17JUL2020 20:30 | Fatigue | Moderate | 1 | | 16JUL2020 10:45 |
| | | 17JUL2020 20:30 | Myalgia | Mild | 1 | | 16JUL2020 10:45 |
| | | 17JUL2020 20:30 | Arthralgia | Mild | 1 | | 16JUL2020 10:45 |
| | | 17JUL2020 20:30 | Chills | Mild | 1 | | 16JUL2020 10:45 |
| | | 17JUL2020 20:30 | Loss of Appetite | Moderate | 1 | | 16JUL2020 10:45 |
| | | 17JUL2020 20:30 | Malaise | Moderate | 1 | | 16JUL2020 10:45 |
| | | 18JUL2020 18:30 | Nausea | Mild | 2 | | 16JUL2020 10:45 |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|------------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 10197 | 18JUL2020 18:30 | Headache | Mild | 2 | | 16JUL2020 10:45 |
| | | 18JUL2020 18:30 | Fatigue | Mild | 2 | | 16JUL2020 10:45 |
| | | 18JUL2020 18:30 | Myalgia | Mild | 2 | | 16JUL2020 10:45 |
| | | 18JUL2020 18:30 | Arthralgia | Mild | 2 | | 16JUL2020 10:45 |
| | | 18JUL2020 18:30 | Loss of Appetite | Mild | 2 | | 16JUL2020 10:45 |
| | | 18JUL2020 18:30 | Malaise | Mild | 2 | | 16JUL2020 10:45 |
| | | 19JUL2020 18:20 | Arthralgia | Mild | 3 | | 16JUL2020 10:45 |
| | | 20JUL2020 18:00 | Myalgia | Mild | 4 | | 16JUL2020 10:45 |
| | | 21JUL2020 16:00 | Arthralgia | Mild | 5 | | 16JUL2020 10:45 |
| | | 06AUG2020 22:00 | Nausea | Moderate | 21 | 0 | 16JUL2020 10:45 |
| | | 06AUG2020 22:00 | Vomiting | Moderate | 21 | 0 | 16JUL2020 10:45 |
| | | 06AUG2020 22:00 | Diarrhea | Severe | 21 | 0 | 16JUL2020 10:45 |
| | | 06AUG2020 22:00 | Headache | Mild | 21 | 0 | 16JUL2020 10:45 |
| | | 06AUG2020 22:00 | Fatigue | Moderate | 21 | 0 | 16JUL2020 10:45 |
| | | 06AUG2020 22:00 | Myalgia | Mild | 21 | 0 | 16JUL2020 10:45 |
| | | 06AUG2020 22:00 | Arthralgia | Mild | 21 | 0 | 16JUL2020 10:45 |
| | | 06AUG2020 22:00 | Chills | Severe | 21 | 0 | 16JUL2020 10:45 |
| 06AUG2020 22:00 | Loss of Appetite | Severe | 21 | 0 | 16JUL2020 10:45 | | |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-----------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 10197 | 06AUG2020 22:00 | Malaise | Severe | 21 | 0 | 16JUL2020 10:45 |
| | | 06AUG2020 22:00 | Fever | Moderate | 21 | 0 | 16JUL2020 10:45 |
| | | 07AUG2020 18:30 | Nausea | Moderate | 22 | 1 | 16JUL2020 10:45 |
| | | 07AUG2020 18:30 | Vomiting | Mild | 22 | 1 | 16JUL2020 10:45 |
| | | 07AUG2020 18:30 | Diarrhea | Severe | 22 | 1 | 16JUL2020 10:45 |
| | | 07AUG2020 18:30 | Headache | Severe | 22 | 1 | 16JUL2020 10:45 |
| | | 07AUG2020 18:30 | Fatigue | Severe | 22 | 1 | 16JUL2020 10:45 |
| | | 07AUG2020 18:30 | Myalgia | Moderate | 22 | 1 | 16JUL2020 10:45 |
| | | 07AUG2020 18:30 | Arthralgia | Mild | 22 | 1 | 16JUL2020 10:45 |
| | | 07AUG2020 18:30 | Chills | Severe | 22 | 1 | 16JUL2020 10:45 |
| | | 07AUG2020 18:30 | Loss of Appetite | Severe | 22 | 1 | 16JUL2020 10:45 |
| | | 07AUG2020 18:30 | Malaise | Severe | 22 | 1 | 16JUL2020 10:45 |
| | | 07AUG2020 18:30 | Fever | Moderate | 22 | 1 | 16JUL2020 10:45 |
| | | 08AUG2020 18:30 | Nausea | Moderate | 23 | 2 | 16JUL2020 10:45 |
| | | 08AUG2020 18:30 | Vomiting | Mild | 23 | 2 | 16JUL2020 10:45 |
| | | 08AUG2020 18:30 | Diarrhea | Severe | 23 | 2 | 16JUL2020 10:45 |
| | | 08AUG2020 18:30 | Headache | Moderate | 23 | 2 | 16JUL2020 10:45 |
| 08AUG2020 18:30 | Fatigue | Moderate | 23 | 2 | 16JUL2020 10:45 | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 10197 | 08AUG2020 18:30 | Myalgia | Mild | 23 | 2 | 16JUL2020 10:45 |
| | | 08AUG2020 18:30 | Arthralgia | Mild | 23 | 2 | 16JUL2020 10:45 |
| | | 08AUG2020 18:30 | Chills | Mild | 23 | 2 | 16JUL2020 10:45 |
| | | 08AUG2020 18:30 | Loss of Appetite | Moderate | 23 | 2 | 16JUL2020 10:45 |
| | | 08AUG2020 18:30 | Malaise | Severe | 23 | 2 | 16JUL2020 10:45 |
| | | 09AUG2020 18:00 | Nausea | Mild | 24 | 3 | 16JUL2020 10:45 |
| | | 09AUG2020 18:00 | Diarrhea | Mild | 24 | 3 | 16JUL2020 10:45 |
| | | 09AUG2020 18:00 | Headache | Mild | 24 | 3 | 16JUL2020 10:45 |
| | | 09AUG2020 18:00 | Fatigue | Mild | 24 | 3 | 16JUL2020 10:45 |
| | | 09AUG2020 18:00 | Arthralgia | Mild | 24 | 3 | 16JUL2020 10:45 |
| | | 09AUG2020 18:00 | Malaise | Mild | 24 | 3 | 16JUL2020 10:45 |
| | | 10AUG2020 17:15 | Fatigue | Mild | 25 | 4 | 16JUL2020 10:45 |
| | | 10AUG2020 17:15 | Myalgia | Mild | 25 | 4 | 16JUL2020 10:45 |
| | | 10AUG2020 17:15 | Arthralgia | Mild | 25 | 4 | 16JUL2020 10:45 |
| | | 11AUG2020 18:00 | Myalgia | Mild | 26 | 5 | 16JUL2020 10:45 |
| 12AUG2020 16:00 | Myalgia | Mild | 27 | 6 | 16JUL2020 10:45 | | |
| 30 µg Younger | 10016 | 29APR2020 | Nausea | Moderate | 0 | | 29APR2020 9:03 |
| | | 29APR2020 | Headache | Moderate | 0 | | 29APR2020 9:03 |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 10016 | 29APR2020 | Fatigue | Mild | 0 | | 29APR2020 9:03 |
| | | 29APR2020 | Myalgia | Mild | 0 | | 29APR2020 9:03 |
| | | 29APR2020 | Arthralgia | Moderate | 0 | | 29APR2020 9:03 |
| | | 29APR2020 | Malaise | Mild | 0 | | 29APR2020 9:03 |
| | | 30APR2020 20:50 | Headache | Mild | 1 | | 29APR2020 9:03 |
| | | 30APR2020 20:50 | Fatigue | Mild | 1 | | 29APR2020 9:03 |
| | | 30APR2020 20:50 | Myalgia | Moderate | 1 | | 29APR2020 9:03 |
| | | 30APR2020 20:50 | Arthralgia | Moderate | 1 | | 29APR2020 9:03 |
| | | 30APR2020 20:50 | Malaise | Mild | 1 | | 29APR2020 9:03 |
| | | 01MAY2020 21:00 | Headache | Mild | 2 | | 29APR2020 9:03 |
| | | 02MAY2020 20:30 | Headache | Mild | 3 | | 29APR2020 9:03 |
| | | 20MAY2020 20:13 | Headache | Severe | 21 | 0 | 29APR2020 9:03 |
| | | 20MAY2020 20:13 | Fatigue | Moderate | 21 | 0 | 29APR2020 9:03 |
| | | 20MAY2020 20:13 | Myalgia | Moderate | 21 | 0 | 29APR2020 9:03 |
| | | 20MAY2020 20:13 | Arthralgia | Severe | 21 | 0 | 29APR2020 9:03 |
| | | 20MAY2020 20:13 | Chills | Severe | 21 | 0 | 29APR2020 9:03 |
| | | 20MAY2020 20:13 | Malaise | Severe | 21 | 0 | 29APR2020 9:03 |
| | | 21MAY2020 21:30 | Headache | Severe | 22 | 1 | 29APR2020 9:03 |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 10016 | 21MAY2020 21:30 | Myalgia | Mild | 22 | 1 | 29APR2020 9:03 |
| | | 21MAY2020 21:30 | Arthralgia | Mild | 22 | 1 | 29APR2020 9:03 |
| | | 21MAY2020 21:30 | Chills | Moderate | 22 | 1 | 29APR2020 9:03 |
| | | 21MAY2020 21:30 | Malaise | Moderate | 22 | 1 | 29APR2020 9:03 |
| | 10020 | 20MAY2020 19:01 | Arthralgia | Mild | 21 | 0 | 29APR2020 10:06 |
| | | 21MAY2020 19:06 | Arthralgia | Mild | 22 | 1 | 29APR2020 10:06 |
| | 10021 | 05MAY2020 20:01 | Headache | Mild | 0 | | 05MAY2020 8:30 |
| | | 05MAY2020 20:01 | Fatigue | Mild | 0 | | 05MAY2020 8:30 |
| | | 06MAY2020 20:01 | Headache | Mild | 1 | | 05MAY2020 8:30 |
| | | 06MAY2020 20:01 | Chills | Mild | 1 | | 05MAY2020 8:30 |
| | | 06MAY2020 20:01 | Malaise | Mild | 1 | | 05MAY2020 8:30 |
| | | 10MAY2020 20:00 | Malaise | Mild | 5 | | 05MAY2020 8:30 |
| | | 26MAY2020 20:00 | Headache | Severe | 21 | 0 | 05MAY2020 8:30 |
| | | 26MAY2020 20:00 | Fatigue | Mild | 21 | 0 | 05MAY2020 8:30 |
| | | 26MAY2020 20:00 | Myalgia | Severe | 21 | 0 | 05MAY2020 8:30 |
| | | 26MAY2020 20:00 | Chills | Mild | 21 | 0 | 05MAY2020 8:30 |
| 26MAY2020 20:00 | | Malaise | Severe | 21 | 0 | 05MAY2020 8:30 | |
| 27MAY2020 20:00 | | Headache | Moderate | 22 | 1 | 05MAY2020 8:30 | |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 10021 | 27MAY2020 20:00 | Myalgia | Moderate | 22 | 1 | 05MAY2020 8:30 |
| | | 27MAY2020 20:00 | Chills | Mild | 22 | 1 | 05MAY2020 8:30 |
| | | 27MAY2020 20:00 | Malaise | Moderate | 22 | 1 | 05MAY2020 8:30 |
| | | 28MAY2020 20:00 | Headache | Moderate | 23 | 2 | 05MAY2020 8:30 |
| | | 28MAY2020 20:00 | Myalgia | Moderate | 23 | 2 | 05MAY2020 8:30 |
| | | 28MAY2020 20:00 | Malaise | Moderate | 23 | 2 | 05MAY2020 8:30 |
| | | 29MAY2020 20:00 | Headache | Mild | 24 | 3 | 05MAY2020 8:30 |
| | | 29MAY2020 20:00 | Myalgia | Mild | 24 | 3 | 05MAY2020 8:30 |
| | | 29MAY2020 20:00 | Malaise | Mild | 24 | 3 | 05MAY2020 8:30 |
| | 10028 | 07MAY2020 21:27 | Headache | Mild | 0 | | 07MAY2020 8:30 |
| | | 08MAY2020 21:40 | Headache | Mild | 1 | | 07MAY2020 8:30 |
| | | 28MAY2020 22:00 | Headache | Moderate | 21 | 0 | 07MAY2020 8:30 |
| | | 28MAY2020 22:00 | Fatigue | Moderate | 21 | 0 | 07MAY2020 8:30 |
| | | 28MAY2020 22:00 | Myalgia | Moderate | 21 | 0 | 07MAY2020 8:30 |
| | | 28MAY2020 22:00 | Arthralgia | Moderate | 21 | 0 | 07MAY2020 8:30 |
| | | 28MAY2020 22:00 | Chills | Moderate | 21 | 0 | 07MAY2020 8:30 |
| | | 28MAY2020 22:00 | Malaise | Moderate | 21 | 0 | 07MAY2020 8:30 |
| | | 29MAY2020 22:00 | Nausea | Moderate | 22 | 1 | 07MAY2020 8:30 |
| Program: Lsaf_sysR_1.sas (Page 35 of 92) | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|--|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 10028 | 29MAY2020 22:00 | Headache | Moderate | 22 | 1 | 07MAY2020 8:30 |
| | | 29MAY2020 22:00 | Fatigue | Moderate | 22 | 1 | 07MAY2020 8:30 |
| | | 29MAY2020 22:00 | Myalgia | Moderate | 22 | 1 | 07MAY2020 8:30 |
| | | 29MAY2020 22:00 | Arthralgia | Moderate | 22 | 1 | 07MAY2020 8:30 |
| | | 29MAY2020 22:00 | Chills | Moderate | 22 | 1 | 07MAY2020 8:30 |
| | | 29MAY2020 22:00 | Loss of Appetite | Moderate | 22 | 1 | 07MAY2020 8:30 |
| | | 29MAY2020 22:00 | Malaise | Moderate | 22 | 1 | 07MAY2020 8:30 |
| | 10031 | 07MAY2020 22:00 | Headache | Moderate | 0 | | 07MAY2020 9:00 |
| | | 07MAY2020 22:00 | Fatigue | Moderate | 0 | | 07MAY2020 9:00 |
| | | 07MAY2020 22:00 | Myalgia | Severe | 0 | | 07MAY2020 9:00 |
| | | 07MAY2020 22:00 | Arthralgia | Severe | 0 | | 07MAY2020 9:00 |
| | | 07MAY2020 22:00 | Chills | Moderate | 0 | | 07MAY2020 9:00 |
| | | 07MAY2020 22:00 | Loss of Appetite | Mild | 0 | | 07MAY2020 9:00 |
| | | 07MAY2020 22:00 | Malaise | Severe | 0 | | 07MAY2020 9:00 |
| | | 07MAY2020 22:00 | Fever | Moderate | 0 | | 07MAY2020 9:00 |
| | | 08MAY2020 21:00 | Fatigue | Mild | 1 | | 07MAY2020 9:00 |
| | | 08MAY2020 21:00 | Myalgia | Moderate | 1 | | 07MAY2020 9:00 |
| | | 08MAY2020 21:00 | Arthralgia | Mild | 1 | | 07MAY2020 9:00 |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 10031 | 08MAY2020 21:00 | Malaise | Mild | 1 | | 07MAY2020 9:00 |
| | | 09MAY2020 22:00 | Fatigue | Mild | 2 | | 07MAY2020 9:00 |
| | | 28MAY2020 22:00 | Headache | Severe | 21 | 0 | 07MAY2020 9:00 |
| | | 28MAY2020 22:00 | Fatigue | Mild | 21 | 0 | 07MAY2020 9:00 |
| | | 28MAY2020 22:00 | Myalgia | Severe | 21 | 0 | 07MAY2020 9:00 |
| | | 28MAY2020 22:00 | Arthralgia | Severe | 21 | 0 | 07MAY2020 9:00 |
| | | 28MAY2020 22:00 | Chills | Severe | 21 | 0 | 07MAY2020 9:00 |
| | | 28MAY2020 22:00 | Malaise | Severe | 21 | 0 | 07MAY2020 9:00 |
| | | 28MAY2020 22:00 | Fever | Mild | 21 | 0 | 07MAY2020 9:00 |
| | | 29MAY2020 22:00 | Headache | Severe | 22 | 1 | 07MAY2020 9:00 |
| | | 29MAY2020 22:00 | Fatigue | Moderate | 22 | 1 | 07MAY2020 9:00 |
| | | 29MAY2020 22:00 | Myalgia | Moderate | 22 | 1 | 07MAY2020 9:00 |
| | | 29MAY2020 22:00 | Arthralgia | Moderate | 22 | 1 | 07MAY2020 9:00 |
| | | 29MAY2020 22:00 | Chills | Moderate | 22 | 1 | 07MAY2020 9:00 |
| | | 29MAY2020 22:00 | Loss of Appetite | Moderate | 22 | 1 | 07MAY2020 9:00 |
| | | 29MAY2020 22:00 | Malaise | Severe | 22 | 1 | 07MAY2020 9:00 |
| | | 30MAY2020 22:00 | Headache | Mild | 23 | 2 | 07MAY2020 9:00 |
| | | 30MAY2020 22:00 | Myalgia | Mild | 23 | 2 | 07MAY2020 9:00 |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-----------------|-----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 10031 | 30MAY2020 22:00 | Arthralgia | Mild | 23 | 2 | 07MAY2020 9:00 |
| | | 30MAY2020 22:00 | Chills | Mild | 23 | 2 | 07MAY2020 9:00 |
| | | 30MAY2020 22:00 | Malaise | Mild | 23 | 2 | 07MAY2020 9:00 |
| | | 31MAY2020 22:00 | Myalgia | Mild | 24 | 3 | 07MAY2020 9:00 |
| | | 31MAY2020 22:00 | Malaise | Mild | 24 | 3 | 07MAY2020 9:00 |
| | 10032 | 05MAY2020 19:00 | Headache | Mild | 0 | | 05MAY2020 9:00 |
| | | 05MAY2020 19:00 | Fatigue | Mild | 0 | | 05MAY2020 9:00 |
| | | 06MAY2020 18:34 | Loss of Appetite | Mild | 1 | | 05MAY2020 9:00 |
| | | 06MAY2020 18:34 | Malaise | Mild | 1 | | 05MAY2020 9:00 |
| | | 26MAY2020 19:20 | Headache | Mild | 21 | 0 | 05MAY2020 9:00 |
| | | 27MAY2020 18:35 | Headache | Mild | 22 | 1 | 05MAY2020 9:00 |
| | | 27MAY2020 18:35 | Fatigue | Moderate | 22 | 1 | 05MAY2020 9:00 |
| | | 27MAY2020 18:35 | Myalgia | Moderate | 22 | 1 | 05MAY2020 9:00 |
| | | 27MAY2020 18:35 | Arthralgia | Moderate | 22 | 1 | 05MAY2020 9:00 |
| | | 27MAY2020 18:35 | Loss of Appetite | Mild | 22 | 1 | 05MAY2020 9:00 |
| 27MAY2020 18:35 | Malaise | Moderate | 22 | 1 | 05MAY2020 9:00 | | |
| 27MAY2020 18:35 | Fever | Mild | 22 | 1 | 05MAY2020 9:00 | | |
| 10034 | 05MAY2020 22:05 | Headache | Moderate | 0 | | 05MAY2020 9:30 | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 10034 | 05MAY2020 22:05 | Fatigue | Moderate | 0 | | 05MAY2020 9:30 |
| | | 05MAY2020 22:05 | Myalgia | Moderate | 0 | | 05MAY2020 9:30 |
| | | 05MAY2020 22:05 | Chills | Severe | 0 | | 05MAY2020 9:30 |
| | | 05MAY2020 22:05 | Malaise | Mild | 0 | | 05MAY2020 9:30 |
| | | 06MAY2020 20:10 | Headache | Mild | 1 | | 05MAY2020 9:30 |
| | | 06MAY2020 20:10 | Fatigue | Moderate | 1 | | 05MAY2020 9:30 |
| | | 06MAY2020 20:10 | Loss of Appetite | Mild | 1 | | 05MAY2020 9:30 |
| | | 06MAY2020 20:10 | Malaise | Mild | 1 | | 05MAY2020 9:30 |
| | | 08MAY2020 12:15 | Fatigue | Mild | 3 | | 05MAY2020 9:30 |
| | | 26MAY2020 23:00 | Nausea | Mild | 21 | 0 | 05MAY2020 9:30 |
| | | 26MAY2020 23:00 | Headache | Severe | 21 | 0 | 05MAY2020 9:30 |
| | | 26MAY2020 23:00 | Fatigue | Severe | 21 | 0 | 05MAY2020 9:30 |
| | | 26MAY2020 23:00 | Myalgia | Moderate | 21 | 0 | 05MAY2020 9:30 |
| | | 26MAY2020 23:00 | Arthralgia | Mild | 21 | 0 | 05MAY2020 9:30 |
| | | 26MAY2020 23:00 | Chills | Severe | 21 | 0 | 05MAY2020 9:30 |
| | | 26MAY2020 23:00 | Malaise | Severe | 21 | 0 | 05MAY2020 9:30 |
| | | 26MAY2020 23:00 | Fever | Mild | 21 | 0 | 05MAY2020 9:30 |
| | | 27MAY2020 21:00 | Headache | Mild | 22 | 1 | 05MAY2020 9:30 |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 10034 | 27MAY2020 21:00 | Fatigue | Mild | 22 | 1 | 05MAY2020 9:30 |
| | | 27MAY2020 21:00 | Malaise | Mild | 22 | 1 | 05MAY2020 9:30 |
| | 10037 | 06MAY2020 20:00 | Headache | Mild | 1 | | 05MAY2020 10:00 |
| | | 07MAY2020 21:00 | Headache | Mild | 2 | | 05MAY2020 10:00 |
| | | 07MAY2020 21:00 | Fatigue | Mild | 2 | | 05MAY2020 10:00 |
| | | 07MAY2020 21:00 | Malaise | Mild | 2 | | 05MAY2020 10:00 |
| | | 10MAY2020 21:00 | Fatigue | Mild | 5 | | 05MAY2020 10:00 |
| | | 26MAY2020 21:00 | Nausea | Mild | 21 | 0 | 05MAY2020 10:00 |
| | | 26MAY2020 21:00 | Headache | Moderate | 21 | 0 | 05MAY2020 10:00 |
| | | 26MAY2020 21:00 | Fatigue | Severe | 21 | 0 | 05MAY2020 10:00 |
| | | 26MAY2020 21:00 | Myalgia | Mild | 21 | 0 | 05MAY2020 10:00 |
| | | 26MAY2020 21:00 | Chills | Mild | 21 | 0 | 05MAY2020 10:00 |
| | | 26MAY2020 21:00 | Malaise | Mild | 21 | 0 | 05MAY2020 10:00 |
| | | 27MAY2020 21:00 | Nausea | Mild | 22 | 1 | 05MAY2020 10:00 |
| | | 27MAY2020 21:00 | Headache | Moderate | 22 | 1 | 05MAY2020 10:00 |
| | | 27MAY2020 21:00 | Fatigue | Moderate | 22 | 1 | 05MAY2020 10:00 |
| | | 27MAY2020 21:00 | Myalgia | Mild | 22 | 1 | 05MAY2020 10:00 |
| 27MAY2020 21:00 | Chills | Mild | 22 | 1 | 05MAY2020 10:00 | | |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|-----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 10037 | 27MAY2020 21:00 | Malaise | Mild | 22 | 1 | 05MAY2020 10:00 |
| | | 28MAY2020 21:00 | Nausea | Mild | 23 | 2 | 05MAY2020 10:00 |
| | | 28MAY2020 21:00 | Headache | Mild | 23 | 2 | 05MAY2020 10:00 |
| | | 28MAY2020 21:00 | Fatigue | Mild | 23 | 2 | 05MAY2020 10:00 |
| | | 28MAY2020 21:00 | Malaise | Mild | 23 | 2 | 05MAY2020 10:00 |
| | | 29MAY2020 21:00 | Headache | Mild | 24 | 3 | 05MAY2020 10:00 |
| | | 29MAY2020 21:00 | Fatigue | Mild | 24 | 3 | 05MAY2020 10:00 |
| | | 29MAY2020 21:00 | Malaise | Mild | 24 | 3 | 05MAY2020 10:00 |
| | | 30MAY2020 21:00 | Fatigue | Mild | 25 | 4 | 05MAY2020 10:00 |
| | | 30MAY2020 21:00 | Malaise | Mild | 25 | 4 | 05MAY2020 10:00 |
| | | 31MAY2020 21:00 | Malaise | Mild | 26 | 5 | 05MAY2020 10:00 |
| | | 01JUN2020 21:00 | Headache | Mild | 27 | 6 | 05MAY2020 10:00 |
| | | 01JUN2020 21:00 | Malaise | Mild | 27 | 6 | 05MAY2020 10:00 |
| | | 10038 | 07MAY2020 21:00 | Myalgia | Mild | 0 | |
| 10039 | 07MAY2020 22:00 | Headache | Severe | 0 | | 07MAY2020 10:00 | |
| | 07MAY2020 22:00 | Fatigue | Severe | 0 | | 07MAY2020 10:00 | |
| | 07MAY2020 22:00 | Myalgia | Severe | 0 | | 07MAY2020 10:00 | |
| | 07MAY2020 22:00 | Arthralgia | Severe | 0 | | 07MAY2020 10:00 | |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 10039 | 07MAY2020 22:00 | Chills | Severe | 0 | | 07MAY2020 10:00 |
| | | 07MAY2020 22:00 | Malaise | Severe | 0 | | 07MAY2020 10:00 |
| | | 08MAY2020 22:00 | Headache | Moderate | 1 | | 07MAY2020 10:00 |
| | | 08MAY2020 22:00 | Fatigue | Moderate | 1 | | 07MAY2020 10:00 |
| | | 08MAY2020 22:00 | Myalgia | Moderate | 1 | | 07MAY2020 10:00 |
| | | 08MAY2020 22:00 | Arthralgia | Moderate | 1 | | 07MAY2020 10:00 |
| | | 08MAY2020 22:00 | Malaise | Mild | 1 | | 07MAY2020 10:00 |
| | | 28MAY2020 22:00 | Headache | Severe | 21 | 0 | 07MAY2020 10:00 |
| | | 28MAY2020 22:00 | Fatigue | Severe | 21 | 0 | 07MAY2020 10:00 |
| | | 28MAY2020 22:00 | Myalgia | Severe | 21 | 0 | 07MAY2020 10:00 |
| | | 28MAY2020 22:00 | Arthralgia | Severe | 21 | 0 | 07MAY2020 10:00 |
| | | 28MAY2020 22:00 | Chills | Severe | 21 | 0 | 07MAY2020 10:00 |
| | | 28MAY2020 22:00 | Loss of Appetite | Severe | 21 | 0 | 07MAY2020 10:00 |
| | | 28MAY2020 22:00 | Malaise | Severe | 21 | 0 | 07MAY2020 10:00 |
| | | 28MAY2020 22:00 | Fever | Severe | 21 | 0 | 07MAY2020 10:00 |
| | | 29MAY2020 22:00 | Headache | Moderate | 22 | 1 | 07MAY2020 10:00 |
| | | 29MAY2020 22:00 | Fatigue | Mild | 22 | 1 | 07MAY2020 10:00 |
| | | 29MAY2020 22:00 | Myalgia | Mild | 22 | 1 | 07MAY2020 10:00 |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|---------------|--|-------------------------|-------------------|---------------------|---|---|---------------------------------|--|
| 30 µg Younger | 10039 | 29MAY2020 22:00 | Arthralgia | Mild | 22 | 1 | 07MAY2020 10:00 | |
| | | 29MAY2020 22:00 | Malaise | Mild | 22 | 1 | 07MAY2020 10:00 | |
| | 10043 | 07MAY2020 20:00 | Headache | Moderate | 0 | | 07MAY2020 10:30 | |
| | | 08MAY2020 20:00 | Headache | Moderate | 1 | | 07MAY2020 10:30 | |
| | | 09MAY2020 20:00 | Headache | Moderate | 2 | | 07MAY2020 10:30 | |
| | | 10MAY2020 20:00 | Headache | Moderate | 3 | | 07MAY2020 10:30 | |
| | | 11MAY2020 20:00 | Headache | Moderate | 4 | | 07MAY2020 10:30 | |
| | | 12MAY2020 20:00 | Headache | Moderate | 5 | | 07MAY2020 10:30 | |
| | | 13MAY2020 20:00 | Headache | Mild | 6 | | 07MAY2020 10:30 | |
| | | 28MAY2020 20:00 | Headache | Mild | 21 | 0 | 07MAY2020 10:30 | |
| | | 29MAY2020 20:00 | Headache | Mild | 22 | 1 | 07MAY2020 10:30 | |
| | | 29MAY2020 20:00 | Fatigue | Mild | 22 | 1 | 07MAY2020 10:30 | |
| | | 29MAY2020 20:00 | Chills | Mild | 22 | 1 | 07MAY2020 10:30 | |
| | | 29MAY2020 20:00 | Malaise | Mild | 22 | 1 | 07MAY2020 10:30 | |
| | | 30MAY2020 20:00 | Headache | Mild | 23 | 2 | 07MAY2020 10:30 | |
| | 31MAY2020 20:00 | Headache | Mild | 24 | 3 | 07MAY2020 10:30 | | |
| | 10047 | 07MAY2020 23:00 | Diarrhea | Mild | 0 | | 07MAY2020 11:00 | |
| | | 07MAY2020 23:00 | Headache | Mild | 0 | | 07MAY2020 11:00 | |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 10047 | 07MAY2020 23:00 | Fatigue | Mild | 0 | | 07MAY2020 11:00 |
| | | 07MAY2020 23:00 | Myalgia | Mild | 0 | | 07MAY2020 11:00 |
| | | 07MAY2020 23:00 | Arthralgia | Mild | 0 | | 07MAY2020 11:00 |
| | | 07MAY2020 23:00 | Malaise | Mild | 0 | | 07MAY2020 11:00 |
| | | 08MAY2020 23:45 | Fatigue | Mild | 1 | | 07MAY2020 11:00 |
| | | 08MAY2020 23:45 | Myalgia | Mild | 1 | | 07MAY2020 11:00 |
| | | 08MAY2020 23:45 | Arthralgia | Mild | 1 | | 07MAY2020 11:00 |
| | | 10MAY2020 23:40 | Headache | Mild | 3 | | 07MAY2020 11:00 |
| | | 10MAY2020 23:40 | Fatigue | Mild | 3 | | 07MAY2020 11:00 |
| | | 11MAY2020 0:30 | Fatigue | Mild | 4 | | 07MAY2020 11:00 |
| | | 28MAY2020 23:55 | Headache | Mild | 21 | 0 | 07MAY2020 11:00 |
| | | 28MAY2020 23:55 | Fatigue | Mild | 21 | 0 | 07MAY2020 11:00 |
| | | 28MAY2020 23:55 | Myalgia | Mild | 21 | 0 | 07MAY2020 11:00 |
| | | 28MAY2020 23:55 | Arthralgia | Mild | 21 | 0 | 07MAY2020 11:00 |
| | | 28MAY2020 23:55 | Malaise | Mild | 21 | 0 | 07MAY2020 11:00 |
| | | 29MAY2020 21:00 | Headache | Moderate | 22 | 1 | 07MAY2020 11:00 |
| | | 29MAY2020 21:00 | Fatigue | Moderate | 22 | 1 | 07MAY2020 11:00 |
| | | 29MAY2020 21:00 | Myalgia | Moderate | 22 | 1 | 07MAY2020 11:00 |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 10047 | 29MAY2020 21:00 | Arthralgia | Moderate | 22 | 1 | 07MAY2020 11:00 |
| | | 29MAY2020 21:00 | Chills | Mild | 22 | 1 | 07MAY2020 11:00 |
| | | 29MAY2020 21:00 | Loss of Appetite | Mild | 22 | 1 | 07MAY2020 11:00 |
| | | 29MAY2020 21:00 | Malaise | Moderate | 22 | 1 | 07MAY2020 11:00 |
| | | 29MAY2020 21:00 | Fever | Mild | 22 | 1 | 07MAY2020 11:00 |
| | | 30MAY2020 23:55 | Fatigue | Mild | 23 | 2 | 07MAY2020 11:00 |
| | | 30MAY2020 23:55 | Myalgia | Mild | 23 | 2 | 07MAY2020 11:00 |
| | | 30MAY2020 23:55 | Arthralgia | Mild | 23 | 2 | 07MAY2020 11:00 |
| | | 31MAY2020 22:00 | Fatigue | Mild | 24 | 3 | 07MAY2020 11:00 |
| 50 µg Younger | 10049 | 12MAY2020 19:30 | Headache | Mild | 0 | | 12MAY2020 9:10 |
| | | 12MAY2020 19:30 | Fatigue | Mild | 0 | | 12MAY2020 9:10 |
| | | 12MAY2020 19:30 | Malaise | Mild | 0 | | 12MAY2020 9:10 |
| | | 13MAY2020 13:00 | Headache | Mild | 1 | | 12MAY2020 9:10 |
| | | 13MAY2020 13:00 | Chills | Mild | 1 | | 12MAY2020 9:10 |
| | | 13MAY2020 13:00 | Loss of Appetite | Mild | 1 | | 12MAY2020 9:10 |
| | | 13MAY2020 13:00 | Malaise | Mild | 1 | | 12MAY2020 9:10 |
| | | 13MAY2020 13:00 | Fever | Mild | 1 | | 12MAY2020 9:10 |
| | | 15MAY2020 13:40 | Myalgia | Mild | 3 | | 12MAY2020 9:10 |
| Program: Lsaf_sysR_1.sas (Page 45 of 92) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10049 | 02JUN2020 23:00 | Headache | Severe | 21 | 0 | 12MAY2020 9:10 |
| | | 02JUN2020 23:00 | Fatigue | Moderate | 21 | 0 | 12MAY2020 9:10 |
| | | 02JUN2020 23:00 | Arthralgia | Mild | 21 | 0 | 12MAY2020 9:10 |
| | | 02JUN2020 23:00 | Loss of Appetite | Severe | 21 | 0 | 12MAY2020 9:10 |
| | | 02JUN2020 23:00 | Malaise | Severe | 21 | 0 | 12MAY2020 9:10 |
| | | 02JUN2020 23:00 | Fever | Severe | 21 | 0 | 12MAY2020 9:10 |
| | | 03JUN2020 7:15 | Headache | Severe | 22 | 1 | 12MAY2020 9:10 |
| | | 03JUN2020 7:15 | Fatigue | Moderate | 22 | 1 | 12MAY2020 9:10 |
| | | 03JUN2020 7:15 | Arthralgia | Mild | 22 | 1 | 12MAY2020 9:10 |
| | | 03JUN2020 7:15 | Loss of Appetite | Severe | 22 | 1 | 12MAY2020 9:10 |
| | | 03JUN2020 7:15 | Malaise | Severe | 22 | 1 | 12MAY2020 9:10 |
| | | 03JUN2020 7:15 | Fever | Mild | 22 | 1 | 12MAY2020 9:10 |
| | | 04JUN2020 9:00 | Headache | Moderate | 23 | 2 | 12MAY2020 9:10 |
| | | 04JUN2020 9:00 | Fatigue | Mild | 23 | 2 | 12MAY2020 9:10 |
| | | 04JUN2020 9:00 | Loss of Appetite | Moderate | 23 | 2 | 12MAY2020 9:10 |
| | | 04JUN2020 9:00 | Malaise | Mild | 23 | 2 | 12MAY2020 9:10 |
| | 05JUN2020 9:00 | Loss of Appetite | Mild | 24 | 3 | 12MAY2020 9:10 | |
| | 10050 | 15MAY2020 19:18 | Headache | Moderate | 0 | | 15MAY2020 8:45 |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10050 | 15MAY2020 19:18 | Fatigue | Moderate | 0 | | 15MAY2020 8:45 |
| | | 15MAY2020 19:18 | Myalgia | Mild | 0 | | 15MAY2020 8:45 |
| | | 15MAY2020 19:18 | Loss of Appetite | Mild | 0 | | 15MAY2020 8:45 |
| | | 15MAY2020 19:18 | Malaise | Moderate | 0 | | 15MAY2020 8:45 |
| | | 16MAY2020 19:45 | Headache | Mild | 1 | | 15MAY2020 8:45 |
| | | 16MAY2020 19:45 | Fatigue | Moderate | 1 | | 15MAY2020 8:45 |
| | | 16MAY2020 19:45 | Chills | Mild | 1 | | 15MAY2020 8:45 |
| | | 16MAY2020 19:45 | Loss of Appetite | Mild | 1 | | 15MAY2020 8:45 |
| | | 16MAY2020 19:45 | Malaise | Moderate | 1 | | 15MAY2020 8:45 |
| | | 17MAY2020 20:19 | Fatigue | Moderate | 2 | | 15MAY2020 8:45 |
| | | 17MAY2020 20:19 | Loss of Appetite | Mild | 2 | | 15MAY2020 8:45 |
| | | 17MAY2020 20:19 | Malaise | Moderate | 2 | | 15MAY2020 8:45 |
| | | 18MAY2020 20:03 | Headache | Mild | 3 | | 15MAY2020 8:45 |
| | | 18MAY2020 20:03 | Fatigue | Mild | 3 | | 15MAY2020 8:45 |
| | | 18MAY2020 20:03 | Malaise | Mild | 3 | | 15MAY2020 8:45 |
| | | 19MAY2020 21:22 | Fatigue | Mild | 4 | | 15MAY2020 8:45 |
| | | 19MAY2020 21:22 | Malaise | Mild | 4 | | 15MAY2020 8:45 |
| | | 20MAY2020 19:24 | Headache | Mild | 5 | | 15MAY2020 8:45 |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10050 | 20MAY2020 19:24 | Malaise | Mild | 5 | | 15MAY2020 8:45 |
| | | 21MAY2020 20:14 | Fatigue | Mild | 6 | | 15MAY2020 8:45 |
| | | 21MAY2020 20:14 | Malaise | Mild | 6 | | 15MAY2020 8:45 |
| | 10053 | 12MAY2020 20:00 | Fatigue | Mild | 0 | | 12MAY2020 10:13 |
| | | 12MAY2020 20:00 | Chills | Mild | 0 | | 12MAY2020 10:13 |
| | | 13MAY2020 20:00 | Chills | Mild | 1 | | 12MAY2020 10:13 |
| | | 13MAY2020 20:00 | Fever | Moderate | 1 | | 12MAY2020 10:13 |
| | | 02JUN2020 20:00 | Headache | Mild | 21 | 0 | 12MAY2020 10:13 |
| | | 02JUN2020 20:00 | Fatigue | Mild | 21 | 0 | 12MAY2020 10:13 |
| | | 02JUN2020 20:00 | Chills | Mild | 21 | 0 | 12MAY2020 10:13 |
| | | 02JUN2020 20:00 | Loss of Appetite | Mild | 21 | 0 | 12MAY2020 10:13 |
| | | 02JUN2020 20:00 | Malaise | Moderate | 21 | 0 | 12MAY2020 10:13 |
| | | 03JUN2020 20:00 | Headache | Mild | 22 | 1 | 12MAY2020 10:13 |
| | | 03JUN2020 20:00 | Fatigue | Mild | 22 | 1 | 12MAY2020 10:13 |
| | | 03JUN2020 20:00 | Chills | Mild | 22 | 1 | 12MAY2020 10:13 |
| | | 03JUN2020 20:00 | Loss of Appetite | Mild | 22 | 1 | 12MAY2020 10:13 |
| | | 03JUN2020 20:00 | Malaise | Mild | 22 | 1 | 12MAY2020 10:13 |
| | | 03JUN2020 20:00 | Fever | Moderate | 22 | 1 | 12MAY2020 10:13 |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10055 | 13MAY2020 17:30 | Headache | Mild | 0 | | 13MAY2020 9:13 |
| | | 13MAY2020 17:30 | Fatigue | Mild | 0 | | 13MAY2020 9:13 |
| | | 14MAY2020 21:30 | Headache | Mild | 1 | | 13MAY2020 9:13 |
| | | 14MAY2020 21:30 | Arthralgia | Moderate | 1 | | 13MAY2020 9:13 |
| | | 15MAY2020 22:00 | Arthralgia | Moderate | 2 | | 13MAY2020 9:13 |
| | | 03JUN2020 21:40 | Myalgia | Mild | 21 | 0 | 13MAY2020 9:13 |
| | | 03JUN2020 21:40 | Arthralgia | Moderate | 21 | 0 | 13MAY2020 9:13 |
| | | 03JUN2020 21:40 | Loss of Appetite | Moderate | 21 | 0 | 13MAY2020 9:13 |
| | | 03JUN2020 21:40 | Malaise | Mild | 21 | 0 | 13MAY2020 9:13 |
| | 10056 | 13MAY2020 20:30 | Nausea | Mild | 0 | | 13MAY2020 10:16 |
| | | 13MAY2020 20:30 | Headache | Mild | 0 | | 13MAY2020 10:16 |
| | | 13MAY2020 20:30 | Fatigue | Mild | 0 | | 13MAY2020 10:16 |
| | | 13MAY2020 20:30 | Malaise | Mild | 0 | | 13MAY2020 10:16 |
| | | 14MAY2020 20:30 | Nausea | Mild | 1 | | 13MAY2020 10:16 |
| | | 14MAY2020 20:30 | Headache | Moderate | 1 | | 13MAY2020 10:16 |
| | | 14MAY2020 20:30 | Fatigue | Moderate | 1 | | 13MAY2020 10:16 |
| | | 14MAY2020 20:30 | Myalgia | Moderate | 1 | | 13MAY2020 10:16 |
| | | 14MAY2020 20:30 | Arthralgia | Mild | 1 | | 13MAY2020 10:16 |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10056 | 14MAY2020 20:30 | Chills | Moderate | 1 | | 13MAY2020 10:16 |
| | | 14MAY2020 20:30 | Loss of Appetite | Mild | 1 | | 13MAY2020 10:16 |
| | | 14MAY2020 20:30 | Malaise | Moderate | 1 | | 13MAY2020 10:16 |
| | | 15MAY2020 20:30 | Headache | Mild | 2 | | 13MAY2020 10:16 |
| | | 15MAY2020 20:30 | Fatigue | Mild | 2 | | 13MAY2020 10:16 |
| | | 15MAY2020 20:30 | Myalgia | Mild | 2 | | 13MAY2020 10:16 |
| | | 15MAY2020 20:30 | Malaise | Mild | 2 | | 13MAY2020 10:16 |
| | | 16MAY2020 20:30 | Fatigue | Mild | 3 | | 13MAY2020 10:16 |
| | | 17MAY2020 20:30 | Fatigue | Mild | 4 | | 13MAY2020 10:16 |
| | | 03JUN2020 21:30 | Nausea | Mild | 21 | 0 | 13MAY2020 10:16 |
| | | 03JUN2020 21:30 | Headache | Severe | 21 | 0 | 13MAY2020 10:16 |
| | | 03JUN2020 21:30 | Fatigue | Severe | 21 | 0 | 13MAY2020 10:16 |
| | | 03JUN2020 21:30 | Myalgia | Moderate | 21 | 0 | 13MAY2020 10:16 |
| | | 03JUN2020 21:30 | Arthralgia | Moderate | 21 | 0 | 13MAY2020 10:16 |
| | | 03JUN2020 21:30 | Chills | Severe | 21 | 0 | 13MAY2020 10:16 |
| | | 03JUN2020 21:30 | Loss of Appetite | Severe | 21 | 0 | 13MAY2020 10:16 |
| | | 03JUN2020 21:30 | Malaise | Severe | 21 | 0 | 13MAY2020 10:16 |
| | | 03JUN2020 21:30 | Fever | Severe | 21 | 0 | 13MAY2020 10:16 |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10056 | 04JUN2020 21:30 | Headache | Severe | 22 | 1 | 13MAY2020 10:16 |
| | | 04JUN2020 21:30 | Fatigue | Severe | 22 | 1 | 13MAY2020 10:16 |
| | | 04JUN2020 21:30 | Myalgia | Moderate | 22 | 1 | 13MAY2020 10:16 |
| | | 04JUN2020 21:30 | Arthralgia | Moderate | 22 | 1 | 13MAY2020 10:16 |
| | | 04JUN2020 21:30 | Chills | Severe | 22 | 1 | 13MAY2020 10:16 |
| | | 04JUN2020 21:30 | Loss of Appetite | Moderate | 22 | 1 | 13MAY2020 10:16 |
| | | 04JUN2020 21:30 | Malaise | Severe | 22 | 1 | 13MAY2020 10:16 |
| | | 04JUN2020 21:30 | Fever | Moderate | 22 | 1 | 13MAY2020 10:16 |
| | | 05JUN2020 21:30 | Headache | Mild | 23 | 2 | 13MAY2020 10:16 |
| | | 05JUN2020 21:30 | Fatigue | Mild | 23 | 2 | 13MAY2020 10:16 |
| | | 05JUN2020 21:30 | Myalgia | Mild | 23 | 2 | 13MAY2020 10:16 |
| | | 05JUN2020 21:30 | Arthralgia | Mild | 23 | 2 | 13MAY2020 10:16 |
| | | 06JUN2020 21:30 | Fatigue | Mild | 24 | 3 | 13MAY2020 10:16 |
| | | 06JUN2020 21:30 | Myalgia | Mild | 24 | 3 | 13MAY2020 10:16 |
| | 10057 | 15MAY2020 20:00 | Myalgia | Mild | 0 | | 15MAY2020 9:15 |
| | | 15MAY2020 20:00 | Arthralgia | Mild | 0 | | 15MAY2020 9:15 |
| | | 15MAY2020 20:00 | Chills | Moderate | 0 | | 15MAY2020 9:15 |
| | | 15MAY2020 20:00 | Malaise | Mild | 0 | | 15MAY2020 9:15 |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10057 | 16MAY2020 20:00 | Fatigue | Moderate | 1 | | 15MAY2020 9:15 |
| | | 16MAY2020 20:00 | Myalgia | Severe | 1 | | 15MAY2020 9:15 |
| | | 16MAY2020 20:00 | Arthralgia | Severe | 1 | | 15MAY2020 9:15 |
| | | 16MAY2020 20:00 | Chills | Severe | 1 | | 15MAY2020 9:15 |
| | | 16MAY2020 20:00 | Malaise | Moderate | 1 | | 15MAY2020 9:15 |
| | | 05JUN2020 20:37 | Fatigue | Moderate | 21 | 0 | 15MAY2020 9:15 |
| | | 05JUN2020 20:37 | Myalgia | Moderate | 21 | 0 | 15MAY2020 9:15 |
| | | 05JUN2020 20:37 | Arthralgia | Mild | 21 | 0 | 15MAY2020 9:15 |
| | | 05JUN2020 20:37 | Chills | Moderate | 21 | 0 | 15MAY2020 9:15 |
| | | 05JUN2020 20:37 | Malaise | Mild | 21 | 0 | 15MAY2020 9:15 |
| | | 06JUN2020 18:30 | Diarrhea | Mild | 22 | 1 | 15MAY2020 9:15 |
| | | 06JUN2020 18:30 | Headache | Mild | 22 | 1 | 15MAY2020 9:15 |
| | | 06JUN2020 18:30 | Fatigue | Mild | 22 | 1 | 15MAY2020 9:15 |
| | | 06JUN2020 18:30 | Myalgia | Mild | 22 | 1 | 15MAY2020 9:15 |
| | | 06JUN2020 18:30 | Arthralgia | Mild | 22 | 1 | 15MAY2020 9:15 |
| | | 06JUN2020 18:30 | Chills | Mild | 22 | 1 | 15MAY2020 9:15 |
| | | 06JUN2020 18:30 | Malaise | Mild | 22 | 1 | 15MAY2020 9:15 |
| | | 07JUN2020 14:00 | Headache | Mild | 23 | 2 | 15MAY2020 9:15 |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10057 | 07JUN2020 14:00 | Myalgia | Mild | 23 | 2 | 15MAY2020 9:15 |
| | 10059 | 13MAY2020 16:50 | Headache | Mild | 0 | | 13MAY2020 10:46 |
| | | 14MAY2020 17:00 | Nausea | Moderate | 1 | | 13MAY2020 10:46 |
| | | 14MAY2020 17:00 | Headache | Moderate | 1 | | 13MAY2020 10:46 |
| | | 14MAY2020 17:00 | Fatigue | Severe | 1 | | 13MAY2020 10:46 |
| | | 14MAY2020 17:00 | Myalgia | Mild | 1 | | 13MAY2020 10:46 |
| | | 14MAY2020 17:00 | Arthralgia | Mild | 1 | | 13MAY2020 10:46 |
| | | 14MAY2020 17:00 | Chills | Moderate | 1 | | 13MAY2020 10:46 |
| | | 14MAY2020 17:00 | Loss of Appetite | Severe | 1 | | 13MAY2020 10:46 |
| | | 14MAY2020 17:00 | Malaise | Severe | 1 | | 13MAY2020 10:46 |
| | | 14MAY2020 17:00 | Fever | Moderate | 1 | | 13MAY2020 10:46 |
| | | 15MAY2020 17:50 | Nausea | Moderate | 2 | | 13MAY2020 10:46 |
| | | 15MAY2020 17:50 | Headache | Moderate | 2 | | 13MAY2020 10:46 |
| | | 15MAY2020 17:50 | Fatigue | Moderate | 2 | | 13MAY2020 10:46 |
| | | 15MAY2020 17:50 | Myalgia | Mild | 2 | | 13MAY2020 10:46 |
| | | 15MAY2020 17:50 | Arthralgia | Mild | 2 | | 13MAY2020 10:46 |
| | | 15MAY2020 17:50 | Loss of Appetite | Severe | 2 | | 13MAY2020 10:46 |
| | | 15MAY2020 17:50 | Malaise | Moderate | 2 | | 13MAY2020 10:46 |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|------------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10059 | 16MAY2020 17:30 | Nausea | Mild | 3 | | 13MAY2020 10:46 |
| | | 16MAY2020 17:30 | Headache | Mild | 3 | | 13MAY2020 10:46 |
| | | 16MAY2020 17:30 | Fatigue | Moderate | 3 | | 13MAY2020 10:46 |
| | | 16MAY2020 17:30 | Loss of Appetite | Moderate | 3 | | 13MAY2020 10:46 |
| | | 16MAY2020 17:30 | Malaise | Moderate | 3 | | 13MAY2020 10:46 |
| | | 17MAY2020 17:15 | Headache | Mild | 4 | | 13MAY2020 10:46 |
| | | 17MAY2020 17:15 | Fatigue | Mild | 4 | | 13MAY2020 10:46 |
| | | 17MAY2020 17:15 | Loss of Appetite | Mild | 4 | | 13MAY2020 10:46 |
| | | 17MAY2020 17:15 | Malaise | Mild | 4 | | 13MAY2020 10:46 |
| | | 18MAY2020 19:00 | Headache | Mild | 5 | | 13MAY2020 10:46 |
| | | 18MAY2020 19:00 | Loss of Appetite | Mild | 5 | | 13MAY2020 10:46 |
| | | 03JUN2020 17:30 | Nausea | Moderate | 21 | 0 | 13MAY2020 10:46 |
| | | 03JUN2020 17:30 | Headache | Severe | 21 | 0 | 13MAY2020 10:46 |
| | | 03JUN2020 17:30 | Fatigue | Severe | 21 | 0 | 13MAY2020 10:46 |
| | | 03JUN2020 17:30 | Myalgia | Moderate | 21 | 0 | 13MAY2020 10:46 |
| | | 03JUN2020 17:30 | Arthralgia | Moderate | 21 | 0 | 13MAY2020 10:46 |
| | | 03JUN2020 17:30 | Chills | Severe | 21 | 0 | 13MAY2020 10:46 |
| 03JUN2020 17:30 | Loss of Appetite | Moderate | 21 | 0 | 13MAY2020 10:46 | | |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10059 | 03JUN2020 17:30 | Malaise | Severe | 21 | 0 | 13MAY2020 10:46 |
| | | 03JUN2020 17:30 | Fever | Moderate | 21 | 0 | 13MAY2020 10:46 |
| | | 04JUN2020 10:00 | Nausea | Severe | 22 | 1 | 13MAY2020 10:46 |
| | | 04JUN2020 10:00 | Headache | Severe | 22 | 1 | 13MAY2020 10:46 |
| | | 04JUN2020 10:00 | Fatigue | Severe | 22 | 1 | 13MAY2020 10:46 |
| | | 04JUN2020 10:00 | Myalgia | Moderate | 22 | 1 | 13MAY2020 10:46 |
| | | 04JUN2020 10:00 | Arthralgia | Moderate | 22 | 1 | 13MAY2020 10:46 |
| | | 04JUN2020 10:00 | Chills | Severe | 22 | 1 | 13MAY2020 10:46 |
| | | 04JUN2020 10:00 | Loss of Appetite | Severe | 22 | 1 | 13MAY2020 10:46 |
| | | 04JUN2020 10:00 | Malaise | Severe | 22 | 1 | 13MAY2020 10:46 |
| | | 04JUN2020 10:00 | Fever | Mild | 22 | 1 | 13MAY2020 10:46 |
| | | 05JUN2020 18:00 | Nausea | Severe | 23 | 2 | 13MAY2020 10:46 |
| | | 05JUN2020 18:00 | Headache | Severe | 23 | 2 | 13MAY2020 10:46 |
| | | 05JUN2020 18:00 | Fatigue | Moderate | 23 | 2 | 13MAY2020 10:46 |
| | | 05JUN2020 18:00 | Myalgia | Moderate | 23 | 2 | 13MAY2020 10:46 |
| | | 05JUN2020 18:00 | Arthralgia | Moderate | 23 | 2 | 13MAY2020 10:46 |
| | | 05JUN2020 18:00 | Chills | Mild | 23 | 2 | 13MAY2020 10:46 |
| | | 05JUN2020 18:00 | Loss of Appetite | Severe | 23 | 2 | 13MAY2020 10:46 |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10059 | 05JUN2020 18:00 | Malaise | Moderate | 23 | 2 | 13MAY2020 10:46 |
| | | 06JUN2020 17:00 | Nausea | Mild | 24 | 3 | 13MAY2020 10:46 |
| | | 06JUN2020 17:00 | Headache | Mild | 24 | 3 | 13MAY2020 10:46 |
| | | 06JUN2020 17:00 | Fatigue | Mild | 24 | 3 | 13MAY2020 10:46 |
| | | 06JUN2020 17:00 | Myalgia | Mild | 24 | 3 | 13MAY2020 10:46 |
| | | 06JUN2020 17:00 | Arthralgia | Mild | 24 | 3 | 13MAY2020 10:46 |
| | | 06JUN2020 17:00 | Loss of Appetite | Mild | 24 | 3 | 13MAY2020 10:46 |
| | | 06JUN2020 17:00 | Malaise | Mild | 24 | 3 | 13MAY2020 10:46 |
| | 10060 | 14MAY2020 18:00 | Headache | Severe | 1 | | 13MAY2020 11:16 |
| | | 14MAY2020 18:00 | Fatigue | Moderate | 1 | | 13MAY2020 11:16 |
| | | 14MAY2020 18:00 | Chills | Mild | 1 | | 13MAY2020 11:16 |
| | | 14MAY2020 18:00 | Malaise | Mild | 1 | | 13MAY2020 11:16 |
| | | 04JUN2020 6:00 | Chills | Moderate | 22 | 1 | 13MAY2020 11:16 |
| | | 04JUN2020 6:00 | Loss of Appetite | Moderate | 22 | 1 | 13MAY2020 11:16 |
| | | 04JUN2020 6:00 | Malaise | Moderate | 22 | 1 | 13MAY2020 11:16 |
| | | 04JUN2020 6:00 | Fever | Mild | 22 | 1 | 13MAY2020 11:16 |
| | 10067 | 15MAY2020 22:00 | Headache | Mild | 0 | | 15MAY2020 9:45 |
| | | 15MAY2020 22:00 | Fatigue | Mild | 0 | | 15MAY2020 9:45 |
| Program: Lsaf_sysR_1.sas (Page 56 of 92) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10067 | 15MAY2020 22:00 | Malaise | Mild | 0 | | 15MAY2020 9:45 |
| | | 16MAY2020 22:00 | Headache | Mild | 1 | | 15MAY2020 9:45 |
| | | 05JUN2020 22:00 | Headache | Moderate | 21 | 0 | 15MAY2020 9:45 |
| | | 05JUN2020 22:00 | Fatigue | Mild | 21 | 0 | 15MAY2020 9:45 |
| | | 05JUN2020 22:00 | Myalgia | Moderate | 21 | 0 | 15MAY2020 9:45 |
| | | 05JUN2020 22:00 | Chills | Moderate | 21 | 0 | 15MAY2020 9:45 |
| | | 06JUN2020 22:00 | Headache | Moderate | 22 | 1 | 15MAY2020 9:45 |
| | | 06JUN2020 22:00 | Myalgia | Moderate | 22 | 1 | 15MAY2020 9:45 |
| | 10068 | 15MAY2020 22:30 | Myalgia | Mild | 0 | | 15MAY2020 10:15 |
| | | 16MAY2020 23:00 | Headache | Moderate | 1 | | 15MAY2020 10:15 |
| | | 16MAY2020 23:00 | Fatigue | Mild | 1 | | 15MAY2020 10:15 |
| | | 16MAY2020 23:00 | Myalgia | Moderate | 1 | | 15MAY2020 10:15 |
| | | 16MAY2020 23:00 | Arthralgia | Moderate | 1 | | 15MAY2020 10:15 |
| | | 16MAY2020 23:00 | Chills | Severe | 1 | | 15MAY2020 10:15 |
| | | 16MAY2020 23:00 | Loss of Appetite | Mild | 1 | | 15MAY2020 10:15 |
| | | 16MAY2020 23:00 | Malaise | Moderate | 1 | | 15MAY2020 10:15 |
| | | 17MAY2020 22:30 | Headache | Mild | 2 | | 15MAY2020 10:15 |
| | | 17MAY2020 22:30 | Loss of Appetite | Mild | 2 | | 15MAY2020 10:15 |

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Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10068 | 05JUN2020 22:30 | Nausea | Mild | 21 | 0 | 15MAY2020 10:15 |
| | | 05JUN2020 22:30 | Headache | Moderate | 21 | 0 | 15MAY2020 10:15 |
| | | 05JUN2020 22:30 | Fatigue | Moderate | 21 | 0 | 15MAY2020 10:15 |
| | | 05JUN2020 22:30 | Myalgia | Moderate | 21 | 0 | 15MAY2020 10:15 |
| | | 05JUN2020 22:30 | Arthralgia | Moderate | 21 | 0 | 15MAY2020 10:15 |
| | | 05JUN2020 22:30 | Chills | Moderate | 21 | 0 | 15MAY2020 10:15 |
| | | 05JUN2020 22:30 | Malaise | Moderate | 21 | 0 | 15MAY2020 10:15 |
| | | 06JUN2020 22:00 | Headache | Moderate | 22 | 1 | 15MAY2020 10:15 |
| | | 06JUN2020 22:00 | Fatigue | Mild | 22 | 1 | 15MAY2020 10:15 |
| | | 06JUN2020 22:00 | Myalgia | Moderate | 22 | 1 | 15MAY2020 10:15 |
| | | 06JUN2020 22:00 | Arthralgia | Moderate | 22 | 1 | 15MAY2020 10:15 |
| | | 06JUN2020 22:00 | Chills | Mild | 22 | 1 | 15MAY2020 10:15 |
| | | 06JUN2020 22:00 | Loss of Appetite | Mild | 22 | 1 | 15MAY2020 10:15 |
| | | 06JUN2020 22:00 | Malaise | Moderate | 22 | 1 | 15MAY2020 10:15 |
| | | 07JUN2020 20:30 | Myalgia | Moderate | 23 | 2 | 15MAY2020 10:15 |
| | | 07JUN2020 20:30 | Arthralgia | Mild | 23 | 2 | 15MAY2020 10:15 |
| | | 07JUN2020 20:30 | Malaise | Mild | 23 | 2 | 15MAY2020 10:15 |
| | | 08JUN2020 23:00 | Myalgia | Mild | 24 | 3 | 15MAY2020 10:15 |
| Program: Lsaf_sysR_1.sas (Page 58 of 92) | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | | |
|---------------|----------------|--|-------------------|---------------------|---|---|---------------------------------|--|--|
| 50 µg Younger | 10068 | 08JUN2020 23:00 | Arthralgia | Mild | 24 | 3 | 15MAY2020 10:15 | | |
| | 10070 | 16MAY2020 19:00 | Nausea | Moderate | 1 | | 15MAY2020 10:45 | | |
| | | 16MAY2020 19:00 | Headache | Severe | 1 | | 15MAY2020 10:45 | | |
| | | 16MAY2020 19:00 | Fatigue | Severe | 1 | | 15MAY2020 10:45 | | |
| | | 16MAY2020 19:00 | Myalgia | Severe | 1 | | 15MAY2020 10:45 | | |
| | | 16MAY2020 19:00 | Chills | Severe | 1 | | 15MAY2020 10:45 | | |
| | | 16MAY2020 19:00 | Loss of Appetite | Moderate | 1 | | 15MAY2020 10:45 | | |
| | | 16MAY2020 19:00 | Malaise | Severe | 1 | | 15MAY2020 10:45 | | |
| | | 16MAY2020 19:00 | Fever | Mild | 1 | | 15MAY2020 10:45 | | |
| | | 17MAY2020 19:00 | Nausea | Mild | 2 | | 15MAY2020 10:45 | | |
| | | 17MAY2020 19:00 | Headache | Moderate | 2 | | 15MAY2020 10:45 | | |
| | | 17MAY2020 19:00 | Fatigue | Moderate | 2 | | 15MAY2020 10:45 | | |
| | | 17MAY2020 19:00 | Myalgia | Moderate | 2 | | 15MAY2020 10:45 | | |
| | | 17MAY2020 19:00 | Loss of Appetite | Moderate | 2 | | 15MAY2020 10:45 | | |
| | | 17MAY2020 19:00 | Malaise | Moderate | 2 | | 15MAY2020 10:45 | | |
| | | 18MAY2020 19:15 | Fatigue | Mild | 3 | | 15MAY2020 10:45 | | |
| | | 18MAY2020 19:15 | Loss of Appetite | Mild | 3 | | 15MAY2020 10:45 | | |
| | | 05JUN2020 19:00 | Headache | Moderate | 21 | 0 | 15MAY2020 10:45 | | |
| | | Program: Lsaf_sysR_1.sas (Page 59 of 92) | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|--|-------------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10070 | 05JUN2020 19:00 | Fatigue | Mild | 21 | 0 | 15MAY2020 10:45 |
| | | 05JUN2020 19:00 | Chills | Severe | 21 | 0 | 15MAY2020 10:45 |
| | | 05JUN2020 19:00 | Malaise | Mild | 21 | 0 | 15MAY2020 10:45 |
| | | 06JUN2020 19:00 | Fatigue | Moderate | 22 | 1 | 15MAY2020 10:45 |
| | | 06JUN2020 19:00 | Malaise | Mild | 22 | 1 | 15MAY2020 10:45 |
| | 10073 | 15MAY2020 22:15 | Nausea | Moderate | 0 | | 15MAY2020 11:15 |
| | | 15MAY2020 22:15 | Vomiting | Mild | 0 | | 15MAY2020 11:15 |
| | | 15MAY2020 22:15 | Headache | Moderate | 0 | | 15MAY2020 11:15 |
| | | 15MAY2020 22:15 | Fatigue | Moderate | 0 | | 15MAY2020 11:15 |
| | | 15MAY2020 22:15 | Malaise | Moderate | 0 | | 15MAY2020 11:15 |
| | | 16MAY2020 22:00 | Nausea | Mild | 1 | | 15MAY2020 11:15 |
| | | 16MAY2020 22:00 | Headache | Moderate | 1 | | 15MAY2020 11:15 |
| | | 16MAY2020 22:00 | Fatigue | Mild | 1 | | 15MAY2020 11:15 |
| | | 16MAY2020 22:00 | Chills | Mild | 1 | | 15MAY2020 11:15 |
| | | 16MAY2020 22:00 | Loss of Appetite | Mild | 1 | | 15MAY2020 11:15 |
| | | 16MAY2020 22:00 | Malaise | Mild | 1 | | 15MAY2020 11:15 |
| | | 17MAY2020 22:20 | Diarrhea | Mild | 2 | | 15MAY2020 11:15 |
| | | 17MAY2020 22:20 | Loss of Appetite | Mild | 2 | | 15MAY2020 11:15 |
| | | Program: Lsaf_sysR_1.sas (Page 60 of 92) | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10073 | 05JUN2020 22:23 | Nausea | Moderate | 21 | 0 | 15MAY2020 11:15 |
| | | 05JUN2020 22:23 | Vomiting | Moderate | 21 | 0 | 15MAY2020 11:15 |
| | | 05JUN2020 22:23 | Headache | Severe | 21 | 0 | 15MAY2020 11:15 |
| | | 05JUN2020 22:23 | Fatigue | Severe | 21 | 0 | 15MAY2020 11:15 |
| | | 05JUN2020 22:23 | Chills | Moderate | 21 | 0 | 15MAY2020 11:15 |
| | | 05JUN2020 22:23 | Loss of Appetite | Severe | 21 | 0 | 15MAY2020 11:15 |
| | | 05JUN2020 22:23 | Malaise | Severe | 21 | 0 | 15MAY2020 11:15 |
| | | 05JUN2020 22:23 | Fever | Moderate | 21 | 0 | 15MAY2020 11:15 |
| | | 06JUN2020 16:10 | Nausea | Mild | 22 | 1 | 15MAY2020 11:15 |
| | | 06JUN2020 16:10 | Headache | Severe | 22 | 1 | 15MAY2020 11:15 |
| | | 06JUN2020 16:10 | Fatigue | Severe | 22 | 1 | 15MAY2020 11:15 |
| | | 06JUN2020 16:10 | Chills | Moderate | 22 | 1 | 15MAY2020 11:15 |
| | | 06JUN2020 16:10 | Loss of Appetite | Severe | 22 | 1 | 15MAY2020 11:15 |
| | | 06JUN2020 16:10 | Malaise | Severe | 22 | 1 | 15MAY2020 11:15 |
| | | 06JUN2020 16:10 | Fever | Mild | 22 | 1 | 15MAY2020 11:15 |
| | | 07JUN2020 22:46 | Headache | Mild | 23 | 2 | 15MAY2020 11:15 |
| | | 07JUN2020 22:46 | Fatigue | Mild | 23 | 2 | 15MAY2020 11:15 |
| | | 07JUN2020 22:46 | Loss of Appetite | Moderate | 23 | 2 | 15MAY2020 11:15 |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 50 µg Younger | 10073 | 07JUN2020 22:46 | Malaise | Mild | 23 | 2 | 15MAY2020 11:15 |
| | | 08JUN2020 23:20 | Loss of Appetite | Mild | 24 | 3 | 15MAY2020 11:15 |
| | | 09JUN2020 1:04 | Loss of Appetite | Mild | 25 | 4 | 15MAY2020 11:15 |
| | | 10JUN2020 23:37 | Fatigue | Moderate | 26 | 5 | 15MAY2020 11:15 |
| 60 µg Younger | 10066 | 19MAY2020 21:55 | Headache | Moderate | 0 | | 19MAY2020 8:36 |
| | | 19MAY2020 21:55 | Fatigue | Mild | 0 | | 19MAY2020 8:36 |
| | | 19MAY2020 21:55 | Myalgia | Moderate | 0 | | 19MAY2020 8:36 |
| | | 19MAY2020 21:55 | Chills | Moderate | 0 | | 19MAY2020 8:36 |
| | | 19MAY2020 21:55 | Loss of Appetite | Mild | 0 | | 19MAY2020 8:36 |
| | | 19MAY2020 21:55 | Fever | Severe | 0 | | 19MAY2020 8:36 |
| | | 20MAY2020 21:54 | Headache | Mild | 1 | | 19MAY2020 8:36 |
| | | 20MAY2020 21:54 | Fatigue | Mild | 1 | | 19MAY2020 8:36 |
| | | 20MAY2020 21:54 | Myalgia | Moderate | 1 | | 19MAY2020 8:36 |
| | | 20MAY2020 21:54 | Chills | Mild | 1 | | 19MAY2020 8:36 |
| | | 20MAY2020 21:54 | Loss of Appetite | Mild | 1 | | 19MAY2020 8:36 |
| | | 21MAY2020 21:55 | Headache | Mild | 2 | | 19MAY2020 8:36 |
| | | 21MAY2020 21:55 | Fatigue | Mild | 2 | | 19MAY2020 8:36 |
| | | 21MAY2020 21:55 | Myalgia | Mild | 2 | | 19MAY2020 8:36 |
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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 60 µg Younger | 10066 | 21MAY2020 21:55 | Malaise | Mild | 2 | | 19MAY2020 8:36 |
| | | 22MAY2020 21:55 | Headache | Mild | 3 | | 19MAY2020 8:36 |
| | | 22MAY2020 21:55 | Fatigue | Mild | 3 | | 19MAY2020 8:36 |
| | | 22MAY2020 21:55 | Myalgia | Mild | 3 | | 19MAY2020 8:36 |
| | | 25MAY2020 21:55 | Headache | Mild | 6 | | 19MAY2020 8:36 |
| | | 25MAY2020 21:55 | Fatigue | Mild | 6 | | 19MAY2020 8:36 |
| | 10075 | 22MAY2020 22:05 | Headache | Severe | 0 | | 22MAY2020 8:50 |
| | | 22MAY2020 22:05 | Fatigue | Severe | 0 | | 22MAY2020 8:50 |
| | | 22MAY2020 22:05 | Myalgia | Mild | 0 | | 22MAY2020 8:50 |
| | | 22MAY2020 22:05 | Arthralgia | Mild | 0 | | 22MAY2020 8:50 |
| | | 22MAY2020 22:05 | Chills | Moderate | 0 | | 22MAY2020 8:50 |
| | | 22MAY2020 22:05 | Loss of Appetite | Severe | 0 | | 22MAY2020 8:50 |
| | | 22MAY2020 22:05 | Malaise | Severe | 0 | | 22MAY2020 8:50 |
| | | 22MAY2020 22:05 | Fever | Moderate | 0 | | 22MAY2020 8:50 |
| | | 23MAY2020 22:00 | Headache | Severe | 1 | | 22MAY2020 8:50 |
| | | 23MAY2020 22:00 | Fatigue | Severe | 1 | | 22MAY2020 8:50 |
| | | 23MAY2020 22:00 | Myalgia | Mild | 1 | | 22MAY2020 8:50 |
| | | 23MAY2020 22:00 | Arthralgia | Moderate | 1 | | 22MAY2020 8:50 |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|--|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 60 µg Younger | 10075 | 23MAY2020 22:00 | Chills | Moderate | 1 | | 22MAY2020 8:50 |
| | | 23MAY2020 22:00 | Loss of Appetite | Severe | 1 | | 22MAY2020 8:50 |
| | | 23MAY2020 22:00 | Malaise | Severe | 1 | | 22MAY2020 8:50 |
| | | 23MAY2020 22:00 | Fever | Mild | 1 | | 22MAY2020 8:50 |
| | | 24MAY2020 22:00 | Fatigue | Mild | 2 | | 22MAY2020 8:50 |
| | | 24MAY2020 22:00 | Myalgia | Mild | 2 | | 22MAY2020 8:50 |
| | | 24MAY2020 22:00 | Arthralgia | Mild | 2 | | 22MAY2020 8:50 |
| | | 25MAY2020 22:00 | Diarrhea | Mild | 3 | | 22MAY2020 8:50 |
| | | 25MAY2020 22:00 | Myalgia | Mild | 3 | | 22MAY2020 8:50 |
| | | 26MAY2020 22:00 | Diarrhea | Mild | 4 | | 22MAY2020 8:50 |
| | | 26MAY2020 22:00 | Headache | Mild | 4 | | 22MAY2020 8:50 |
| | 10076 | 22MAY2020 22:00 | Fatigue | Mild | 0 | | 22MAY2020 9:20 |
| | | 22MAY2020 22:00 | Myalgia | Moderate | 0 | | 22MAY2020 9:20 |
| | | 22MAY2020 22:00 | Chills | Mild | 0 | | 22MAY2020 9:20 |
| | | 23MAY2020 22:00 | Myalgia | Mild | 1 | | 22MAY2020 9:20 |
| | 10078 | 22MAY2020 23:15 | Fatigue | Mild | 0 | | 22MAY2020 9:50 |
| | | 22MAY2020 23:15 | Myalgia | Mild | 0 | | 22MAY2020 9:50 |
| | | 22MAY2020 23:15 | Chills | Mild | 0 | | 22MAY2020 9:50 |
| | Program: Lsaf_sysR_1.sas (Page 64 of 92) | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|--|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 60 µg Younger | 10078 | 23MAY2020 22:45 | Myalgia | Moderate | 1 | | 22MAY2020 9:50 |
| | 10083 | 20MAY2020 19:21 | Fatigue | Mild | 0 | | 20MAY2020 9:15 |
| | | 20MAY2020 19:21 | Myalgia | Mild | 0 | | 20MAY2020 9:15 |
| | | 20MAY2020 19:21 | Chills | Mild | 0 | | 20MAY2020 9:15 |
| | | 20MAY2020 19:21 | Loss of Appetite | Mild | 0 | | 20MAY2020 9:15 |
| | | 20MAY2020 19:21 | Malaise | Mild | 0 | | 20MAY2020 9:15 |
| | | 21MAY2020 18:45 | Fatigue | Mild | 1 | | 20MAY2020 9:15 |
| | | 21MAY2020 18:45 | Myalgia | Mild | 1 | | 20MAY2020 9:15 |
| | | 21MAY2020 18:45 | Loss of Appetite | Mild | 1 | | 20MAY2020 9:15 |
| | | 10084 | 22MAY2020 22:00 | Nausea | Mild | 0 | |
| | 22MAY2020 22:00 | | Headache | Mild | 0 | | 22MAY2020 10:20 |
| | 22MAY2020 22:00 | | Fatigue | Mild | 0 | | 22MAY2020 10:20 |
| | 22MAY2020 22:00 | | Myalgia | Mild | 0 | | 22MAY2020 10:20 |
| | 22MAY2020 22:00 | | Chills | Mild | 0 | | 22MAY2020 10:20 |
| | 22MAY2020 22:00 | | Loss of Appetite | Mild | 0 | | 22MAY2020 10:20 |
| | 22MAY2020 22:00 | | Malaise | Mild | 0 | | 22MAY2020 10:20 |
| | 22MAY2020 22:00 | | Fever | Mild | 0 | | 22MAY2020 10:20 |
| | 23MAY2020 20:30 | | Headache | Mild | 1 | | 22MAY2020 10:20 |
| | Program: Lsaf_sysR_1.sas (Page 65 of 92) | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 60 µg Younger | 10084 | 23MAY2020 20:30 | Myalgia | Mild | 1 | | 22MAY2020 10:20 |
| | | 23MAY2020 20:30 | Chills | Mild | 1 | | 22MAY2020 10:20 |
| | 10085 | 22MAY2020 22:44 | Headache | Moderate | 0 | | 22MAY2020 10:50 |
| | | 22MAY2020 22:44 | Fatigue | Mild | 0 | | 22MAY2020 10:50 |
| | | 22MAY2020 22:44 | Myalgia | Moderate | 0 | | 22MAY2020 10:50 |
| | | 22MAY2020 22:44 | Arthralgia | Moderate | 0 | | 22MAY2020 10:50 |
| | | 22MAY2020 22:44 | Chills | Severe | 0 | | 22MAY2020 10:50 |
| | | 22MAY2020 22:44 | Malaise | Severe | 0 | | 22MAY2020 10:50 |
| | | 22MAY2020 22:44 | Fever | Mild | 0 | | 22MAY2020 10:50 |
| | | 23MAY2020 21:50 | Headache | Moderate | 1 | | 22MAY2020 10:50 |
| | | 23MAY2020 21:50 | Fatigue | Mild | 1 | | 22MAY2020 10:50 |
| | | 23MAY2020 21:50 | Myalgia | Moderate | 1 | | 22MAY2020 10:50 |
| | | 23MAY2020 21:50 | Arthralgia | Mild | 1 | | 22MAY2020 10:50 |
| | | 23MAY2020 21:50 | Malaise | Moderate | 1 | | 22MAY2020 10:50 |
| | | 24MAY2020 22:15 | Headache | Mild | 2 | | 22MAY2020 10:50 |
| | | 24MAY2020 22:15 | Myalgia | Mild | 2 | | 22MAY2020 10:50 |
| | | 24MAY2020 22:15 | Malaise | Mild | 2 | | 22MAY2020 10:50 |
| | | 10089 | 20MAY2020 22:00 | Nausea | Severe | 0 | |
| Program: Lsaf_sysR_1.sas (Page 66 of 92) | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|-----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 60 µg Younger | 10089 | 20MAY2020 22:00 | Vomiting | Severe | 0 | | 20MAY2020 9:45 |
| | | 20MAY2020 22:00 | Headache | Moderate | 0 | | 20MAY2020 9:45 |
| | | 20MAY2020 22:00 | Fatigue | Moderate | 0 | | 20MAY2020 9:45 |
| | | 20MAY2020 22:00 | Loss of Appetite | Mild | 0 | | 20MAY2020 9:45 |
| | | 20MAY2020 22:00 | Malaise | Moderate | 0 | | 20MAY2020 9:45 |
| | | 21MAY2020 22:00 | Nausea | Mild | 1 | | 20MAY2020 9:45 |
| | | 21MAY2020 22:00 | Headache | Mild | 1 | | 20MAY2020 9:45 |
| | | 21MAY2020 22:00 | Malaise | Mild | 1 | | 20MAY2020 9:45 |
| | 10093 | 21MAY2020 18:45 | Nausea | Moderate | 1 | | 20MAY2020 10:15 |
| | | 21MAY2020 18:45 | Headache | Severe | 1 | | 20MAY2020 10:15 |
| | | 21MAY2020 18:45 | Fatigue | Moderate | 1 | | 20MAY2020 10:15 |
| | | 21MAY2020 18:45 | Myalgia | Mild | 1 | | 20MAY2020 10:15 |
| | | 21MAY2020 18:45 | Loss of Appetite | Mild | 1 | | 20MAY2020 10:15 |
| | | 21MAY2020 18:45 | Malaise | Mild | 1 | | 20MAY2020 10:15 |
| | | 22MAY2020 20:07 | Myalgia | Mild | 2 | | 20MAY2020 10:15 |
| | 23MAY2020 21:45 | Arthralgia | Mild | 3 | | 20MAY2020 10:15 | |
| | 10096 | 19MAY2020 22:50 | Headache | Mild | 0 | | 19MAY2020 9:08 |
| | | 19MAY2020 22:50 | Myalgia | Moderate | 0 | | 19MAY2020 9:08 |
| Program: Lsaf_sysR_1.sas (Page 67 of 92) | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|--|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 60 µg Younger | 10096 | 19MAY2020 22:50 | Arthralgia | Severe | 0 | | 19MAY2020 9:08 |
| | | 19MAY2020 22:50 | Chills | Mild | 0 | | 19MAY2020 9:08 |
| | | 19MAY2020 22:50 | Malaise | Severe | 0 | | 19MAY2020 9:08 |
| | | 20MAY2020 19:33 | Malaise | Mild | 1 | | 19MAY2020 9:08 |
| | 10103 | 22MAY2020 19:07 | Fatigue | Severe | 0 | | 22MAY2020 11:32 |
| | | 22MAY2020 19:07 | Myalgia | Mild | 0 | | 22MAY2020 11:32 |
| | | 22MAY2020 19:07 | Chills | Severe | 0 | | 22MAY2020 11:32 |
| | | 23MAY2020 15:18 | Fatigue | Mild | 1 | | 22MAY2020 11:32 |
| | | 23MAY2020 15:18 | Myalgia | Mild | 1 | | 22MAY2020 11:32 |
| | | 23MAY2020 15:18 | Chills | Mild | 1 | | 22MAY2020 11:32 |
| | 10104 | 20MAY2020 22:00 | Nausea | Mild | 0 | | 20MAY2020 10:45 |
| | | 20MAY2020 22:00 | Headache | Severe | 0 | | 20MAY2020 10:45 |
| | | 20MAY2020 22:00 | Fatigue | Mild | 0 | | 20MAY2020 10:45 |
| | | 20MAY2020 22:00 | Chills | Mild | 0 | | 20MAY2020 10:45 |
| | | 20MAY2020 22:00 | Malaise | Moderate | 0 | | 20MAY2020 10:45 |
| | | 21MAY2020 22:00 | Headache | Mild | 1 | | 20MAY2020 10:45 |
| | | 21MAY2020 22:00 | Fatigue | Moderate | 1 | | 20MAY2020 10:45 |
| | | 21MAY2020 22:00 | Myalgia | Mild | 1 | | 20MAY2020 10:45 |
| | Program: Lsaf_sysR_1.sas (Page 68 of 92) | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-----------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 60 µg Younger | 10104 | 21MAY2020 22:00 | Arthralgia | Mild | 1 | | 20MAY2020 10:45 |
| | | 21MAY2020 22:00 | Chills | Mild | 1 | | 20MAY2020 10:45 |
| | | 21MAY2020 22:00 | Malaise | Mild | 1 | | 20MAY2020 10:45 |
| 10 µg Older | 10274 | 27AUG2020 20:45 | Headache | Moderate | 0 | | 27AUG2020 9:00 |
| | | 27AUG2020 20:45 | Fatigue | Mild | 0 | | 27AUG2020 9:00 |
| | | 28AUG2020 20:15 | Headache | Mild | 1 | | 27AUG2020 9:00 |
| | | 28AUG2020 20:15 | Loss of Appetite | Mild | 1 | | 27AUG2020 9:00 |
| | | 29AUG2020 20:30 | Fatigue | Mild | 2 | | 27AUG2020 9:00 |
| | | 30AUG2020 19:30 | Loss of Appetite | Mild | 3 | | 27AUG2020 9:00 |
| | | 17SEP2020 20:30 | Headache | Mild | 21 | 0 | 27AUG2020 9:00 |
| | | 17SEP2020 20:30 | Fatigue | Mild | 21 | 0 | 27AUG2020 9:00 |
| | | 18SEP2020 20:00 | Headache | Mild | 22 | 1 | 27AUG2020 9:00 |
| | 10282 | 21AUG2020 19:00 | Nausea | Moderate | 1 | | 20AUG2020 9:33 |
| | | 21AUG2020 19:00 | Vomiting | Moderate | 1 | | 20AUG2020 9:33 |
| | | 21AUG2020 19:00 | Headache | Moderate | 1 | | 20AUG2020 9:33 |
| | | 21AUG2020 19:00 | Fatigue | Mild | 1 | | 20AUG2020 9:33 |
| | | 21AUG2020 19:00 | Malaise | Mild | 1 | | 20AUG2020 9:33 |
| 22AUG2020 19:00 | | Headache | Mild | 2 | | 20AUG2020 9:33 | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|-----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 10 µg Older | 10282 | 10SEP2020 16:00 | Headache | Mild | 21 | 0 | 20AUG2020 9:33 |
| | | 10SEP2020 16:00 | Fatigue | Mild | 21 | 0 | 20AUG2020 9:33 |
| | | 11SEP2020 7:00 | Fatigue | Mild | 22 | 1 | 20AUG2020 9:33 |
| | | 11SEP2020 7:00 | Loss of Appetite | Mild | 22 | 1 | 20AUG2020 9:33 |
| | | 11SEP2020 7:00 | Malaise | Mild | 22 | 1 | 20AUG2020 9:33 |
| | 10283 | 27AUG2020 21:00 | Headache | Mild | 0 | | 27AUG2020 9:30 |
| | | 27AUG2020 21:00 | Myalgia | Mild | 0 | | 27AUG2020 9:30 |
| | | 27AUG2020 21:00 | Malaise | Mild | 0 | | 27AUG2020 9:30 |
| | | 28AUG2020 21:30 | Headache | Mild | 1 | | 27AUG2020 9:30 |
| | | 28AUG2020 21:30 | Myalgia | Mild | 1 | | 27AUG2020 9:30 |
| | | 17SEP2020 21:00 | Headache | Mild | 21 | 0 | 27AUG2020 9:30 |
| | | 17SEP2020 21:00 | Myalgia | Mild | 21 | 0 | 27AUG2020 9:30 |
| | | 18SEP2020 21:00 | Headache | Mild | 22 | 1 | 27AUG2020 9:30 |
| | 18SEP2020 21:00 | Myalgia | Mild | 22 | 1 | 27AUG2020 9:30 | |
| | 10286 | 26AUG2020 18:30 | Headache | Moderate | 1 | | 25AUG2020 8:30 |
| | 10287 | 25AUG2020 21:00 | Headache | Mild | 0 | | 25AUG2020 9:00 |
| | | 26AUG2020 0:00 | Headache | Mild | 1 | | 25AUG2020 9:00 |
| 15SEP2020 23:10 | | Fatigue | Moderate | 21 | 0 | 25AUG2020 9:00 | |
| Program: Lsaf_sysR_1.sas (Page 70 of 92) | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-------------|----------------|--|-------------------|---------------------|---|---|---------------------------------|
| 10 µg Older | 10287 | 15SEP2020 23:10 | Myalgia | Moderate | 21 | 0 | 25AUG2020 9:00 |
| | | 15SEP2020 23:10 | Arthralgia | Mild | 21 | 0 | 25AUG2020 9:00 |
| | | 15SEP2020 23:10 | Chills | Mild | 21 | 0 | 25AUG2020 9:00 |
| | | 15SEP2020 23:10 | Fever | Mild | 21 | 0 | 25AUG2020 9:00 |
| | | 16SEP2020 23:00 | Headache | Mild | 22 | 1 | 25AUG2020 9:00 |
| | | 16SEP2020 23:00 | Myalgia | Mild | 22 | 1 | 25AUG2020 9:00 |
| | | 17SEP2020 0:00 | Headache | Mild | 23 | 2 | 25AUG2020 9:00 |
| | | 17SEP2020 0:00 | Myalgia | Mild | 23 | 2 | 25AUG2020 9:00 |
| | 10288 | 26AUG2020 21:00 | Headache | Severe | 1 | | 25AUG2020 9:30 |
| | | 26AUG2020 21:00 | Fatigue | Severe | 1 | | 25AUG2020 9:30 |
| | | 26AUG2020 21:00 | Myalgia | Moderate | 1 | | 25AUG2020 9:30 |
| | | 26AUG2020 21:00 | Arthralgia | Moderate | 1 | | 25AUG2020 9:30 |
| | | 26AUG2020 21:00 | Chills | Moderate | 1 | | 25AUG2020 9:30 |
| | | 26AUG2020 21:00 | Malaise | Severe | 1 | | 25AUG2020 9:30 |
| | | 27AUG2020 21:00 | Headache | Mild | 2 | | 25AUG2020 9:30 |
| | | 15SEP2020 23:00 | Headache | Severe | 21 | 0 | 25AUG2020 9:30 |
| | | 15SEP2020 23:00 | Myalgia | Mild | 21 | 0 | 25AUG2020 9:30 |
| | | 15SEP2020 23:00 | Arthralgia | Mild | 21 | 0 | 25AUG2020 9:30 |
| | | Program: Lsaf_sysR_1.sas (Page 71 of 92) | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|-------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|-----------------|
| 10 µg Older | 10288 | 15SEP2020 23:00 | Chills | Severe | 21 | 0 | 25AUG2020 9:30 | |
| | | 15SEP2020 23:00 | Malaise | Severe | 21 | 0 | 25AUG2020 9:30 | |
| | | 15SEP2020 23:00 | Fever | Moderate | 21 | 0 | 25AUG2020 9:30 | |
| | | 16SEP2020 23:00 | Headache | Moderate | 22 | 1 | 25AUG2020 9:30 | |
| | | 16SEP2020 23:00 | Myalgia | Mild | 22 | 1 | 25AUG2020 9:30 | |
| | | 16SEP2020 23:00 | Arthralgia | Mild | 22 | 1 | 25AUG2020 9:30 | |
| | | 16SEP2020 23:00 | Chills | Mild | 22 | 1 | 25AUG2020 9:30 | |
| | | 16SEP2020 23:00 | Malaise | Severe | 22 | 1 | 25AUG2020 9:30 | |
| | | 16SEP2020 23:00 | Fever | Mild | 22 | 1 | 25AUG2020 9:30 | |
| | | 17SEP2020 23:00 | Headache | Moderate | 23 | 2 | 25AUG2020 9:30 | |
| | | 17SEP2020 23:00 | Arthralgia | Mild | 23 | 2 | 25AUG2020 9:30 | |
| | | 17SEP2020 23:00 | Chills | Mild | 23 | 2 | 25AUG2020 9:30 | |
| | | 17SEP2020 23:00 | Malaise | Mild | 23 | 2 | 25AUG2020 9:30 | |
| | | 18SEP2020 23:00 | Headache | Mild | 24 | 3 | 25AUG2020 9:30 | |
| | | 19SEP2020 23:00 | Headache | Mild | 25 | 4 | 25AUG2020 9:30 | |
| | | 20SEP2020 23:00 | Headache | Mild | 26 | 5 | 25AUG2020 9:30 | |
| | | 10292 | 27AUG2020 21:05 | Headache | Moderate | 0 | | 27AUG2020 10:00 |
| | | | 27AUG2020 21:05 | Fatigue | Mild | 0 | | 27AUG2020 10:00 |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 10 µg Older | 10292 | 17SEP2020 20:45 | Nausea | Mild | 21 | 0 | 27AUG2020 10:00 |
| | | 17SEP2020 20:45 | Vomiting | Mild | 21 | 0 | 27AUG2020 10:00 |
| | | 17SEP2020 20:45 | Headache | Severe | 21 | 0 | 27AUG2020 10:00 |
| | 10298 | 28AUG2020 20:08 | Fatigue | Mild | 1 | | 27AUG2020 10:30 |
| | | 17SEP2020 1:00 | Headache | Mild | 21 | 0 | 27AUG2020 10:30 |
| | | 17SEP2020 1:00 | Myalgia | Mild | 21 | 0 | 27AUG2020 10:30 |
| | | 17SEP2020 1:00 | Arthralgia | Mild | 21 | 0 | 27AUG2020 10:30 |
| | | 17SEP2020 1:00 | Chills | Mild | 21 | 0 | 27AUG2020 10:30 |
| | | 17SEP2020 1:00 | Malaise | Mild | 21 | 0 | 27AUG2020 10:30 |
| | | 18SEP2020 10:00 | Headache | Mild | 22 | 1 | 27AUG2020 10:30 |
| | | 18SEP2020 10:00 | Myalgia | Mild | 22 | 1 | 27AUG2020 10:30 |
| | | 18SEP2020 10:00 | Arthralgia | Mild | 22 | 1 | 27AUG2020 10:30 |
| | | 18SEP2020 10:00 | Chills | Mild | 22 | 1 | 27AUG2020 10:30 |
| | | 18SEP2020 10:00 | Malaise | Mild | 22 | 1 | 27AUG2020 10:30 |
| | | 19SEP2020 16:00 | Headache | Mild | 23 | 2 | 27AUG2020 10:30 |
| | | 19SEP2020 16:00 | Myalgia | Mild | 23 | 2 | 27AUG2020 10:30 |
| | | 19SEP2020 16:00 | Malaise | Mild | 23 | 2 | 27AUG2020 10:30 |
| 20SEP2020 10:00 | Myalgia | Mild | 24 | 3 | 27AUG2020 10:30 | | |
| Program: Lsaf_sysR_1.sas (Page 73 of 92) | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 10 µg Older | 10298 | 20SEP2020 10:00 | Arthralgia | Mild | 24 | 3 | 27AUG2020 10:30 |
| | 10320 | 27AUG2020 19:00 | Fatigue | Mild | 0 | | 27AUG2020 11:00 |
| | | 30AUG2020 19:00 | Headache | Mild | 3 | | 27AUG2020 11:00 |
| | | 30AUG2020 19:00 | Fatigue | Mild | 3 | | 27AUG2020 11:00 |
| | | 31AUG2020 19:00 | Headache | Mild | 4 | | 27AUG2020 11:00 |
| | | 31AUG2020 19:00 | Fatigue | Mild | 4 | | 27AUG2020 11:00 |
| | | 02SEP2020 19:00 | Headache | Mild | 6 | | 27AUG2020 11:00 |
| | | 18SEP2020 10:00 | Headache | Mild | 22 | 1 | 27AUG2020 11:00 |
| | | 18SEP2020 10:00 | Fatigue | Mild | 22 | 1 | 27AUG2020 11:00 |
| | | 18SEP2020 10:00 | Malaise | Mild | 22 | 1 | 27AUG2020 11:00 |
| | | 19SEP2020 10:00 | Headache | Mild | 23 | 2 | 27AUG2020 11:00 |
| | | 19SEP2020 10:00 | Fatigue | Mild | 23 | 2 | 27AUG2020 11:00 |
| | | 19SEP2020 10:00 | Malaise | Mild | 23 | 2 | 27AUG2020 11:00 |
| 20 µg Older | 20207 | 09SEP2020 20:30 | Fatigue | Mild | 0 | | 09SEP2020 9:00 |
| | | 10SEP2020 20:00 | Headache | Moderate | 1 | | 09SEP2020 9:00 |
| | | 10SEP2020 20:00 | Fatigue | Mild | 1 | | 09SEP2020 9:00 |
| | | 10SEP2020 20:00 | Arthralgia | Mild | 1 | | 09SEP2020 9:00 |
| | | 30SEP2020 19:00 | Loss of Appetite | Mild | 21 | 0 | 09SEP2020 9:00 |
| Program: Lsaf_sysR_1.sas (Page 74 of 92) | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-------------|----------------|--|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Older | 20207 | 01OCT2020 20:00 | Headache | Mild | 22 | 1 | 09SEP2020 9:00 |
| | | 01OCT2020 20:00 | Fatigue | Mild | 22 | 1 | 09SEP2020 9:00 |
| | | 01OCT2020 20:00 | Loss of Appetite | Mild | 22 | 1 | 09SEP2020 9:00 |
| | | 01OCT2020 20:00 | Malaise | Mild | 22 | 1 | 09SEP2020 9:00 |
| | | 02OCT2020 20:30 | Loss of Appetite | Mild | 23 | 2 | 09SEP2020 9:00 |
| | | 02OCT2020 20:30 | Malaise | Mild | 23 | 2 | 09SEP2020 9:00 |
| | | 03OCT2020 19:30 | Loss of Appetite | Mild | 24 | 3 | 09SEP2020 9:00 |
| | | 03OCT2020 19:30 | Malaise | Mild | 24 | 3 | 09SEP2020 9:00 |
| | 20211 | 09SEP2020 20:30 | Fatigue | Mild | 1 | | 08SEP2020 8:00 |
| | | 09SEP2020 20:30 | Myalgia | Mild | 1 | | 08SEP2020 8:00 |
| | | 10SEP2020 20:30 | Myalgia | Mild | 2 | | 08SEP2020 8:00 |
| | | 30SEP2020 19:30 | Headache | Moderate | 22 | 0 | 08SEP2020 8:00 |
| | | 30SEP2020 19:30 | Myalgia | Moderate | 22 | 0 | 08SEP2020 8:00 |
| | | 30SEP2020 19:30 | Arthralgia | Moderate | 22 | 0 | 08SEP2020 8:00 |
| | | 30SEP2020 19:30 | Chills | Severe | 22 | 0 | 08SEP2020 8:00 |
| | | 30SEP2020 19:30 | Loss of Appetite | Moderate | 22 | 0 | 08SEP2020 8:00 |
| | | 30SEP2020 19:30 | Malaise | Moderate | 22 | 0 | 08SEP2020 8:00 |
| | | 01OCT2020 19:30 | Nausea | Mild | 23 | 1 | 08SEP2020 8:00 |
| | | Program: Lsaf_sysR_1.sas (Page 75 of 92) | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Older | 20211 | 01OCT2020 19:30 | Headache | Moderate | 23 | 1 | 08SEP2020 8:00 |
| | | 01OCT2020 19:30 | Fatigue | Mild | 23 | 1 | 08SEP2020 8:00 |
| | | 01OCT2020 19:30 | Myalgia | Moderate | 23 | 1 | 08SEP2020 8:00 |
| | | 01OCT2020 19:30 | Arthralgia | Moderate | 23 | 1 | 08SEP2020 8:00 |
| | | 01OCT2020 19:30 | Chills | Moderate | 23 | 1 | 08SEP2020 8:00 |
| | | 01OCT2020 19:30 | Loss of Appetite | Moderate | 23 | 1 | 08SEP2020 8:00 |
| | | 01OCT2020 19:30 | Malaise | Mild | 23 | 1 | 08SEP2020 8:00 |
| | 20220 | 08SEP2020 21:00 | Headache | Mild | 0 | | 08SEP2020 9:00 |
| | | 08SEP2020 21:00 | Fatigue | Mild | 0 | | 08SEP2020 9:00 |
| | | 09SEP2020 21:00 | Headache | Moderate | 1 | | 08SEP2020 9:00 |
| | | 09SEP2020 21:00 | Fatigue | Mild | 1 | | 08SEP2020 9:00 |
| | | 09SEP2020 21:00 | Myalgia | Mild | 1 | | 08SEP2020 9:00 |
| | | 09SEP2020 21:00 | Arthralgia | Mild | 1 | | 08SEP2020 9:00 |
| | | 10SEP2020 21:00 | Headache | Mild | 2 | | 08SEP2020 9:00 |
| | | 10SEP2020 21:00 | Myalgia | Mild | 2 | | 08SEP2020 9:00 |
| | | 10SEP2020 21:00 | Arthralgia | Mild | 2 | | 08SEP2020 9:00 |
| | | 11SEP2020 21:00 | Myalgia | Mild | 3 | | 08SEP2020 9:00 |
| | | 01OCT2020 21:00 | Headache | Moderate | 23 | 1 | 08SEP2020 9:00 |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|-------------|----------------|--|-------------------|---------------------|---|---|---------------------------------|-----------------|
| 20 µg Older | 20220 | 01OCT2020 21:00 | Fatigue | Mild | 23 | 1 | 08SEP2020 9:00 | |
| | | 01OCT2020 21:00 | Myalgia | Mild | 23 | 1 | 08SEP2020 9:00 | |
| | | 01OCT2020 21:00 | Arthralgia | Mild | 23 | 1 | 08SEP2020 9:00 | |
| | | 01OCT2020 21:00 | Malaise | Mild | 23 | 1 | 08SEP2020 9:00 | |
| | | 02OCT2020 21:00 | Myalgia | Mild | 24 | 2 | 08SEP2020 9:00 | |
| | | 03OCT2020 20:00 | Myalgia | Mild | 25 | 3 | 08SEP2020 9:00 | |
| | 20227 | 12SEP2020 2:15 | Headache | Moderate | 1 | | | 11SEP2020 11:30 |
| | | 12SEP2020 2:15 | Fatigue | Mild | 1 | | | 11SEP2020 11:30 |
| | | 13SEP2020 22:10 | Fatigue | Mild | 2 | | | 11SEP2020 11:30 |
| | | 03OCT2020 20:00 | Headache | Moderate | 22 | 1 | | 11SEP2020 11:30 |
| | | 03OCT2020 20:00 | Fatigue | Mild | 22 | 1 | | 11SEP2020 11:30 |
| | | 03OCT2020 20:00 | Myalgia | Severe | 22 | 1 | | 11SEP2020 11:30 |
| | | 03OCT2020 20:00 | Arthralgia | Severe | 22 | 1 | | 11SEP2020 11:30 |
| | | 03OCT2020 20:00 | Chills | Mild | 22 | 1 | | 11SEP2020 11:30 |
| | | 03OCT2020 20:00 | Malaise | Moderate | 22 | 1 | | 11SEP2020 11:30 |
| | | 04OCT2020 21:50 | Headache | Mild | 23 | 2 | | 11SEP2020 11:30 |
| | | 04OCT2020 21:50 | Fatigue | Mild | 23 | 2 | | 11SEP2020 11:30 |
| | | 04OCT2020 21:50 | Myalgia | Moderate | 23 | 2 | | 11SEP2020 11:30 |
| | | Program: Lsaf_sysR_1.sas (Page 77 of 92) | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|-----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Older | 20227 | 04OCT2020 21:50 | Arthralgia | Moderate | 23 | 2 | 11SEP2020 11:30 |
| | | 04OCT2020 21:50 | Malaise | Mild | 23 | 2 | 11SEP2020 11:30 |
| | | 05OCT2020 22:00 | Arthralgia | Mild | 24 | 3 | 11SEP2020 11:30 |
| | 20234 | 11SEP2020 21:15 | Headache | Mild | 2 | | 09SEP2020 9:30 |
| | | 01OCT2020 21:00 | Headache | Mild | 22 | 1 | 09SEP2020 9:30 |
| | 20236 | 12SEP2020 21:46 | Fatigue | Mild | 1 | | 11SEP2020 10:30 |
| | 20237 | 02OCT2020 22:30 | Arthralgia | Mild | 21 | 0 | 11SEP2020 9:00 |
| | | 03OCT2020 23:00 | Headache | Mild | 22 | 1 | 11SEP2020 9:00 |
| | | 03OCT2020 23:00 | Arthralgia | Mild | 22 | 1 | 11SEP2020 9:00 |
| | 20238 | 11SEP2020 19:45 | Diarrhea | Mild | 0 | | 11SEP2020 10:00 |
| | | 12SEP2020 19:30 | Fatigue | Mild | 1 | | 11SEP2020 10:00 |
| | | 12SEP2020 19:30 | Myalgia | Moderate | 1 | | 11SEP2020 10:00 |
| | | 12SEP2020 19:30 | Arthralgia | Moderate | 1 | | 11SEP2020 10:00 |
| | | 12SEP2020 19:30 | Chills | Moderate | 1 | | 11SEP2020 10:00 |
| | | 13SEP2020 19:45 | Myalgia | Moderate | 2 | | 11SEP2020 10:00 |
| 13SEP2020 19:45 | | Arthralgia | Moderate | 2 | | 11SEP2020 10:00 | |
| 14SEP2020 19:30 | Myalgia | Moderate | 3 | | 11SEP2020 10:00 | | |
| | 14SEP2020 19:30 | Arthralgia | Mild | 3 | | 11SEP2020 10:00 | |
| Program: Lsaf_sysR_1.sas (Page 78 of 92) | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-------------|--|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Older | 20238 | 15SEP2020 19:35 | Myalgia | Moderate | 4 | | 11SEP2020 10:00 |
| | | 15SEP2020 19:35 | Arthralgia | Mild | 4 | | 11SEP2020 10:00 |
| | | 16SEP2020 19:30 | Myalgia | Mild | 5 | | 11SEP2020 10:00 |
| | | 02OCT2020 21:12 | Fatigue | Mild | 21 | 0 | 11SEP2020 10:00 |
| | | 02OCT2020 21:12 | Myalgia | Mild | 21 | 0 | 11SEP2020 10:00 |
| | | 02OCT2020 21:12 | Arthralgia | Mild | 21 | 0 | 11SEP2020 10:00 |
| | | 02OCT2020 21:12 | Chills | Mild | 21 | 0 | 11SEP2020 10:00 |
| | | 03OCT2020 21:45 | Myalgia | Moderate | 22 | 1 | 11SEP2020 10:00 |
| | | 03OCT2020 21:45 | Arthralgia | Moderate | 22 | 1 | 11SEP2020 10:00 |
| | | 03OCT2020 21:45 | Chills | Moderate | 22 | 1 | 11SEP2020 10:00 |
| | | 04OCT2020 21:45 | Myalgia | Mild | 23 | 2 | 11SEP2020 10:00 |
| | | 04OCT2020 21:45 | Arthralgia | Mild | 23 | 2 | 11SEP2020 10:00 |
| | 20239 | 11SEP2020 22:05 | Myalgia | Mild | 0 | | 11SEP2020 11:00 |
| | | 02OCT2020 19:30 | Headache | Moderate | 21 | 0 | 11SEP2020 11:00 |
| | | 02OCT2020 19:30 | Chills | Moderate | 21 | 0 | 11SEP2020 11:00 |
| | | 03OCT2020 20:00 | Headache | Moderate | 22 | 1 | 11SEP2020 11:00 |
| | | 03OCT2020 20:00 | Chills | Moderate | 22 | 1 | 11SEP2020 11:00 |
| | | 04OCT2020 20:00 | Headache | Moderate | 23 | 2 | 11SEP2020 11:00 |
| | Program: Lsaf_sysR_1.sas (Page 79 of 92) | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|-----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Older | 20239 | 04OCT2020 20:00 | Chills | Moderate | 23 | 2 | 11SEP2020 11:00 |
| | 20241 | 09SEP2020 21:45 | Myalgia | Mild | 0 | | 09SEP2020 10:30 |
| | | 10SEP2020 21:45 | Myalgia | Mild | 1 | | 09SEP2020 10:30 |
| | | 01OCT2020 9:30 | Headache | Mild | 22 | 1 | 09SEP2020 10:30 |
| | | 01OCT2020 9:30 | Fatigue | Mild | 22 | 1 | 09SEP2020 10:30 |
| | | 01OCT2020 9:30 | Chills | Mild | 22 | 1 | 09SEP2020 10:30 |
| | | 01OCT2020 9:30 | Loss of Appetite | Mild | 22 | 1 | 09SEP2020 10:30 |
| | | 01OCT2020 9:30 | Malaise | Mild | 22 | 1 | 09SEP2020 10:30 |
| | | 01OCT2020 9:30 | Fever | Mild | 22 | 1 | 09SEP2020 10:30 |
| | | 02OCT2020 9:30 | Loss of Appetite | Mild | 23 | 2 | 09SEP2020 10:30 |
| | | 03OCT2020 9:30 | Loss of Appetite | Mild | 24 | 3 | 09SEP2020 10:30 |
| | | 04OCT2020 9:30 | Myalgia | Moderate | 25 | 4 | 09SEP2020 10:30 |
| | | 04OCT2020 9:30 | Loss of Appetite | Mild | 25 | 4 | 09SEP2020 10:30 |
| | | 05OCT2020 9:30 | Myalgia | Moderate | 26 | 5 | 09SEP2020 10:30 |
| | | 05OCT2020 9:30 | Loss of Appetite | Mild | 26 | 5 | 09SEP2020 10:30 |
| | | 06OCT2020 9:30 | Myalgia | Mild | 27 | 6 | 09SEP2020 10:30 |
| 07OCT2020 9:07 | Myalgia | Mild | 28 | 7 | 09SEP2020 10:30 | | |
| 20242 | 10SEP2020 21:20 | Headache | Moderate | 1 | | 09SEP2020 10:00 | |
| Program: Lsaf_sysR_1.sas (Page 80 of 92) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Older | 20242 | 10SEP2020 21:20 | Chills | Mild | 1 | | 09SEP2020 10:00 |
| | 20243 | 11SEP2020 19:00 | Diarrhea | Mild | 0 | | 11SEP2020 9:30 |
| | | 11SEP2020 19:00 | Fatigue | Severe | 0 | | 11SEP2020 9:30 |
| | | 12SEP2020 19:00 | Fatigue | Moderate | 1 | | 11SEP2020 9:30 |
| | | 13SEP2020 19:00 | Headache | Moderate | 2 | | 11SEP2020 9:30 |
| | | 13SEP2020 19:00 | Fatigue | Moderate | 2 | | 11SEP2020 9:30 |
| | | 14SEP2020 19:00 | Nausea | Moderate | 3 | | 11SEP2020 9:30 |
| | | 14SEP2020 19:00 | Headache | Moderate | 3 | | 11SEP2020 9:30 |
| | | 14SEP2020 19:00 | Fatigue | Moderate | 3 | | 11SEP2020 9:30 |
| | | 14SEP2020 19:00 | Malaise | Moderate | 3 | | 11SEP2020 9:30 |
| | | 15SEP2020 19:00 | Headache | Moderate | 4 | | 11SEP2020 9:30 |
| | | 15SEP2020 19:00 | Fatigue | Moderate | 4 | | 11SEP2020 9:30 |
| | | 15SEP2020 19:00 | Chills | Moderate | 4 | | 11SEP2020 9:30 |
| | | 02OCT2020 19:30 | Nausea | Mild | 21 | 0 | 11SEP2020 9:30 |
| | | 02OCT2020 19:30 | Headache | Mild | 21 | 0 | 11SEP2020 9:30 |
| | | 02OCT2020 19:30 | Fatigue | Mild | 21 | 0 | 11SEP2020 9:30 |
| 02OCT2020 19:30 | Malaise | Mild | 21 | 0 | 11SEP2020 9:30 | | |
| 30 µg Older | 10350 | 26SEP2020 20:00 | Headache | Mild | 1 | | 25SEP2020 8:20 |
| Program: Lsaf_sysR_1.sas (Page 81 of 92) | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-------------|--|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Older | 10350 | 26SEP2020 20:00 | Fatigue | Moderate | 1 | | 25SEP2020 8:20 |
| | | 26SEP2020 20:00 | Myalgia | Moderate | 1 | | 25SEP2020 8:20 |
| | | 26SEP2020 20:00 | Malaise | Mild | 1 | | 25SEP2020 8:20 |
| | | 16OCT2020 20:00 | Headache | Moderate | 21 | 0 | 25SEP2020 8:20 |
| | | 16OCT2020 20:00 | Fatigue | Severe | 21 | 0 | 25SEP2020 8:20 |
| | | 16OCT2020 20:00 | Myalgia | Severe | 21 | 0 | 25SEP2020 8:20 |
| | | 16OCT2020 20:00 | Chills | Moderate | 21 | 0 | 25SEP2020 8:20 |
| | | 16OCT2020 20:00 | Loss of Appetite | Mild | 21 | 0 | 25SEP2020 8:20 |
| | | 17OCT2020 20:00 | Fatigue | Moderate | 22 | 1 | 25SEP2020 8:20 |
| | | 17OCT2020 20:00 | Myalgia | Moderate | 22 | 1 | 25SEP2020 8:20 |
| | | 17OCT2020 20:00 | Chills | Mild | 22 | 1 | 25SEP2020 8:20 |
| | | 18OCT2020 20:00 | Fatigue | Mild | 23 | 2 | 25SEP2020 8:20 |
| | | 18OCT2020 20:00 | Myalgia | Mild | 23 | 2 | 25SEP2020 8:20 |
| | 10351 | 25SEP2020 20:45 | Fatigue | Mild | 0 | | 25SEP2020 8:50 |
| | | 25SEP2020 20:45 | Myalgia | Mild | 0 | | 25SEP2020 8:50 |
| | | 26SEP2020 21:40 | Fatigue | Mild | 1 | | 25SEP2020 8:50 |
| | | 26SEP2020 21:40 | Myalgia | Mild | 1 | | 25SEP2020 8:50 |
| | | 16OCT2020 8:50 | Fatigue | Mild | 21 | 0 | 25SEP2020 8:50 |
| | Program: Lsaf_sysR_1.sas (Page 82 of 92) | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|----------------|
| 30 µg Older | 10351 | 16OCT2020 8:50 | Myalgia | Mild | 21 | 0 | 25SEP2020 8:50 | |
| | | 16OCT2020 8:50 | Arthralgia | Mild | 21 | 0 | 25SEP2020 8:50 | |
| | | 16OCT2020 21:00 | Fatigue | Mild | 21 | 0 | 25SEP2020 8:50 | |
| | | 16OCT2020 21:00 | Myalgia | Mild | 21 | 0 | 25SEP2020 8:50 | |
| | | 16OCT2020 21:00 | Arthralgia | Mild | 21 | 0 | 25SEP2020 8:50 | |
| | | 17OCT2020 21:00 | Myalgia | Mild | 22 | 1 | 25SEP2020 8:50 | |
| | | 17OCT2020 21:00 | Arthralgia | Mild | 22 | 1 | 25SEP2020 8:50 | |
| | | 17OCT2020 21:00 | Fever | Mild | 22 | 1 | 25SEP2020 8:50 | |
| | | 18OCT2020 21:00 | Myalgia | Mild | 23 | 2 | 25SEP2020 8:50 | |
| | 10352 | 22SEP2020 21:00 | Fatigue | Mild | 0 | | | 22SEP2020 8:20 |
| | | 13OCT2020 21:30 | Nausea | Mild | 21 | 0 | | 22SEP2020 8:20 |
| | | 13OCT2020 21:30 | Headache | Mild | 21 | 0 | | 22SEP2020 8:20 |
| | | 13OCT2020 21:30 | Malaise | Mild | 21 | 0 | | 22SEP2020 8:20 |
| | | 14OCT2020 22:05 | Nausea | Mild | 22 | 1 | | 22SEP2020 8:20 |
| | | 14OCT2020 22:05 | Headache | Mild | 22 | 1 | | 22SEP2020 8:20 |
| | | 14OCT2020 22:05 | Fatigue | Moderate | 22 | 1 | | 22SEP2020 8:20 |
| | | 14OCT2020 22:05 | Loss of Appetite | Moderate | 22 | 1 | | 22SEP2020 8:20 |
| 14OCT2020 22:05 | Malaise | Mild | 22 | 1 | | 22SEP2020 8:20 | | |
| Program: Lsaf_sysR_1.sas (Page 83 of 92) | | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Older | 10352 | 15OCT2020 23:20 | Fatigue | Mild | 23 | 2 | 22SEP2020 8:20 |
| | 10353 | 22SEP2020 19:00 | Nausea | Moderate | 0 | | 22SEP2020 8:50 |
| | | 22SEP2020 19:00 | Headache | Severe | 0 | | 22SEP2020 8:50 |
| | | 22SEP2020 19:00 | Fatigue | Severe | 0 | | 22SEP2020 8:50 |
| | | 22SEP2020 19:00 | Myalgia | Mild | 0 | | 22SEP2020 8:50 |
| | | 22SEP2020 19:00 | Arthralgia | Mild | 0 | | 22SEP2020 8:50 |
| | | 22SEP2020 19:00 | Loss of Appetite | Mild | 0 | | 22SEP2020 8:50 |
| | | 22SEP2020 19:00 | Malaise | Severe | 0 | | 22SEP2020 8:50 |
| | | 23SEP2020 19:00 | Headache | Moderate | 1 | | 22SEP2020 8:50 |
| | | 23SEP2020 19:00 | Fatigue | Moderate | 1 | | 22SEP2020 8:50 |
| | | 23SEP2020 19:00 | Myalgia | Moderate | 1 | | 22SEP2020 8:50 |
| | | 23SEP2020 19:00 | Arthralgia | Moderate | 1 | | 22SEP2020 8:50 |
| | | 23SEP2020 19:00 | Malaise | Mild | 1 | | 22SEP2020 8:50 |
| | | 24SEP2020 20:00 | Fatigue | Moderate | 2 | | 22SEP2020 8:50 |
| | | 24SEP2020 20:00 | Arthralgia | Moderate | 2 | | 22SEP2020 8:50 |
| | | 24SEP2020 20:00 | Malaise | Mild | 2 | | 22SEP2020 8:50 |
| | | 13OCT2020 22:00 | Headache | Mild | 21 | 0 | 22SEP2020 8:50 |
| | | 13OCT2020 22:00 | Fatigue | Mild | 21 | 0 | 22SEP2020 8:50 |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|-----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Older | 10353 | 13OCT2020 22:00 | Myalgia | Mild | 21 | 0 | 22SEP2020 8:50 |
| | | 13OCT2020 22:00 | Chills | Moderate | 21 | 0 | 22SEP2020 8:50 |
| | | 13OCT2020 22:00 | Loss of Appetite | Mild | 21 | 0 | 22SEP2020 8:50 |
| | | 13OCT2020 22:00 | Malaise | Mild | 21 | 0 | 22SEP2020 8:50 |
| | | 14OCT2020 22:00 | Nausea | Moderate | 22 | 1 | 22SEP2020 8:50 |
| | | 14OCT2020 22:00 | Headache | Moderate | 22 | 1 | 22SEP2020 8:50 |
| | | 14OCT2020 22:00 | Fatigue | Severe | 22 | 1 | 22SEP2020 8:50 |
| | | 14OCT2020 22:00 | Myalgia | Mild | 22 | 1 | 22SEP2020 8:50 |
| | | 14OCT2020 22:00 | Loss of Appetite | Mild | 22 | 1 | 22SEP2020 8:50 |
| | | 14OCT2020 22:00 | Malaise | Moderate | 22 | 1 | 22SEP2020 8:50 |
| | | 14OCT2020 22:00 | Fever | Moderate | 22 | 1 | 22SEP2020 8:50 |
| | | 15OCT2020 22:00 | Headache | Mild | 23 | 2 | 22SEP2020 8:50 |
| | | 15OCT2020 22:00 | Myalgia | Mild | 23 | 2 | 22SEP2020 8:50 |
| | 15OCT2020 22:00 | Loss of Appetite | Mild | 23 | 2 | 22SEP2020 8:50 | |
| | 10358 | 24SEP2020 19:30 | Nausea | Mild | 1 | | 23SEP2020 8:31 |
| | | 24SEP2020 19:30 | Arthralgia | Mild | 1 | | 23SEP2020 8:31 |
| 24SEP2020 19:30 | | Loss of Appetite | Moderate | 1 | | 23SEP2020 8:31 | |
| 25SEP2020 19:30 | | Arthralgia | Mild | 2 | | 23SEP2020 8:31 | |
| Program: Lsaf_sysR_1.sas (Page 85 of 92) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Older | 10358 | 25SEP2020 19:30 | Loss of Appetite | Moderate | 2 | | 23SEP2020 8:31 |
| | | 26SEP2020 20:30 | Arthralgia | Mild | 3 | | 23SEP2020 8:31 |
| | | 26SEP2020 20:30 | Loss of Appetite | Moderate | 3 | | 23SEP2020 8:31 |
| | | 27SEP2020 19:15 | Myalgia | Mild | 4 | | 23SEP2020 8:31 |
| | | 27SEP2020 19:15 | Arthralgia | Mild | 4 | | 23SEP2020 8:31 |
| | | 27SEP2020 19:15 | Chills | Mild | 4 | | 23SEP2020 8:31 |
| | | 27SEP2020 19:15 | Loss of Appetite | Moderate | 4 | | 23SEP2020 8:31 |
| | | 28SEP2020 19:30 | Arthralgia | Mild | 5 | | 23SEP2020 8:31 |
| | | 28SEP2020 19:30 | Chills | Mild | 5 | | 23SEP2020 8:31 |
| | | 28SEP2020 19:30 | Loss of Appetite | Moderate | 5 | | 23SEP2020 8:31 |
| | | 29SEP2020 19:10 | Myalgia | Mild | 6 | | 23SEP2020 8:31 |
| | | 29SEP2020 19:10 | Arthralgia | Mild | 6 | | 23SEP2020 8:31 |
| | | 29SEP2020 19:10 | Loss of Appetite | Moderate | 6 | | 23SEP2020 8:31 |
| | | 14OCT2020 20:15 | Nausea | Mild | 21 | 0 | 23SEP2020 8:31 |
| | | 14OCT2020 20:15 | Vomiting | Moderate | 21 | 0 | 23SEP2020 8:31 |
| | | 14OCT2020 20:15 | Headache | Mild | 21 | 0 | 23SEP2020 8:31 |
| | | 14OCT2020 20:15 | Fatigue | Mild | 21 | 0 | 23SEP2020 8:31 |
| 14OCT2020 20:15 | Arthralgia | Mild | 21 | 0 | 23SEP2020 8:31 | | |
| Program: Lsaf_sysR_1.sas (Page 86 of 92) | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Older | 10358 | 14OCT2020 20:15 | Chills | Severe | 21 | 0 | 23SEP2020 8:31 |
| | | 14OCT2020 20:15 | Loss of Appetite | Mild | 21 | 0 | 23SEP2020 8:31 |
| | | 14OCT2020 20:15 | Malaise | Moderate | 21 | 0 | 23SEP2020 8:31 |
| | | 15OCT2020 19:00 | Nausea | Moderate | 22 | 1 | 23SEP2020 8:31 |
| | | 15OCT2020 19:00 | Headache | Mild | 22 | 1 | 23SEP2020 8:31 |
| | | 15OCT2020 19:00 | Fatigue | Mild | 22 | 1 | 23SEP2020 8:31 |
| | | 15OCT2020 19:00 | Arthralgia | Severe | 22 | 1 | 23SEP2020 8:31 |
| | | 15OCT2020 19:00 | Chills | Mild | 22 | 1 | 23SEP2020 8:31 |
| | | 15OCT2020 19:00 | Loss of Appetite | Mild | 22 | 1 | 23SEP2020 8:31 |
| | | 15OCT2020 19:00 | Malaise | Moderate | 22 | 1 | 23SEP2020 8:31 |
| | | 16OCT2020 18:30 | Arthralgia | Mild | 23 | 2 | 23SEP2020 8:31 |
| | | 16OCT2020 18:30 | Chills | Mild | 23 | 2 | 23SEP2020 8:31 |
| | | 16OCT2020 18:30 | Malaise | Mild | 23 | 2 | 23SEP2020 8:31 |
| | | 17OCT2020 18:30 | Arthralgia | Mild | 24 | 3 | 23SEP2020 8:31 |
| | | 17OCT2020 18:30 | Loss of Appetite | Mild | 24 | 3 | 23SEP2020 8:31 |
| | | 18OCT2020 19:30 | Arthralgia | Mild | 25 | 4 | 23SEP2020 8:31 |
| | | 18OCT2020 19:30 | Loss of Appetite | Mild | 25 | 4 | 23SEP2020 8:31 |
| 19OCT2020 19:00 | Arthralgia | Mild | 26 | 5 | 23SEP2020 8:31 | | |
| Program: Lsaf_sysR_1.sas (Page 87 of 92) | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Older | 10358 | 19OCT2020 19:00 | Loss of Appetite | Mild | 26 | 5 | 23SEP2020 8:31 |
| | | 20OCT2020 18:30 | Arthralgia | Mild | 27 | 6 | 23SEP2020 8:31 |
| | | 20OCT2020 18:30 | Loss of Appetite | Mild | 27 | 6 | 23SEP2020 8:31 |
| | 10360 | 23SEP2020 21:00 | Myalgia | Mild | 0 | | 23SEP2020 9:00 |
| | | 24SEP2020 21:15 | Myalgia | Mild | 1 | | 23SEP2020 9:00 |
| | | 25SEP2020 22:00 | Myalgia | Mild | 2 | | 23SEP2020 9:00 |
| | | 15OCT2020 21:30 | Fatigue | Mild | 22 | 1 | 23SEP2020 9:00 |
| | | 15OCT2020 21:30 | Malaise | Mild | 22 | 1 | 23SEP2020 9:00 |
| | 10361 | 25SEP2020 22:30 | Diarrhea | Mild | 0 | | 25SEP2020 9:20 |
| | | 25SEP2020 22:30 | Headache | Mild | 0 | | 25SEP2020 9:20 |
| | | 25SEP2020 22:30 | Chills | Mild | 0 | | 25SEP2020 9:20 |
| | | 26SEP2020 22:15 | Headache | Moderate | 1 | | 25SEP2020 9:20 |
| | | 26SEP2020 22:15 | Fatigue | Mild | 1 | | 25SEP2020 9:20 |
| | | 26SEP2020 22:15 | Arthralgia | Mild | 1 | | 25SEP2020 9:20 |
| | | 26SEP2020 22:15 | Chills | Mild | 1 | | 25SEP2020 9:20 |
| 26SEP2020 22:15 | | Malaise | Mild | 1 | | 25SEP2020 9:20 | |
| 27SEP2020 23:00 | | Myalgia | Mild | 2 | | 25SEP2020 9:20 | |
| 16OCT2020 22:35 | Headache | Moderate | 21 | 0 | 25SEP2020 9:20 | | |
| Program: Lsaf_sysR_1.sas (Page 88 of 92) | | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-------------|--|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Older | 10361 | 16OCT2020 22:35 | Fatigue | Mild | 21 | 0 | 25SEP2020 9:20 |
| | | 16OCT2020 22:35 | Myalgia | Mild | 21 | 0 | 25SEP2020 9:20 |
| | | 16OCT2020 22:35 | Arthralgia | Mild | 21 | 0 | 25SEP2020 9:20 |
| | | 16OCT2020 22:35 | Chills | Moderate | 21 | 0 | 25SEP2020 9:20 |
| | | 16OCT2020 22:35 | Malaise | Mild | 21 | 0 | 25SEP2020 9:20 |
| | | 16OCT2020 22:35 | Fever | Moderate | 21 | 0 | 25SEP2020 9:20 |
| | | 17OCT2020 23:00 | Headache | Moderate | 22 | 1 | 25SEP2020 9:20 |
| | | 17OCT2020 23:00 | Fatigue | Mild | 22 | 1 | 25SEP2020 9:20 |
| | | 17OCT2020 23:00 | Myalgia | Mild | 22 | 1 | 25SEP2020 9:20 |
| | | 17OCT2020 23:00 | Arthralgia | Mild | 22 | 1 | 25SEP2020 9:20 |
| | | 17OCT2020 23:00 | Chills | Mild | 22 | 1 | 25SEP2020 9:20 |
| | | 17OCT2020 23:00 | Loss of Appetite | Mild | 22 | 1 | 25SEP2020 9:20 |
| | | 17OCT2020 23:00 | Malaise | Mild | 22 | 1 | 25SEP2020 9:20 |
| | 10362 | 26SEP2020 20:45 | Fatigue | Mild | 1 | | 25SEP2020 9:50 |
| | | 26SEP2020 20:45 | Arthralgia | Mild | 1 | | 25SEP2020 9:50 |
| | | 26SEP2020 20:45 | Chills | Mild | 1 | | 25SEP2020 9:50 |
| | | 16OCT2020 20:00 | Headache | Mild | 21 | 0 | 25SEP2020 9:50 |
| | | 16OCT2020 20:00 | Fatigue | Mild | 21 | 0 | 25SEP2020 9:50 |
| | Program: Lsaf_sysR_1.sas (Page 89 of 92) | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-------------|--|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Older | 10362 | 17OCT2020 20:00 | Headache | Mild | 22 | 1 | 25SEP2020 9:50 |
| | | 17OCT2020 20:00 | Myalgia | Mild | 22 | 1 | 25SEP2020 9:50 |
| | | 17OCT2020 20:00 | Arthralgia | Mild | 22 | 1 | 25SEP2020 9:50 |
| | | 18OCT2020 20:00 | Myalgia | Mild | 23 | 2 | 25SEP2020 9:50 |
| | 10363 | 25SEP2020 21:30 | Fatigue | Mild | 0 | | 25SEP2020 10:20 |
| | | 26SEP2020 21:30 | Fatigue | Mild | 1 | | 25SEP2020 10:20 |
| | | 01OCT2020 21:45 | Fatigue | Mild | 6 | | 25SEP2020 10:20 |
| | | 16OCT2020 21:45 | Fatigue | Mild | 21 | 0 | 25SEP2020 10:20 |
| | | 16OCT2020 21:45 | Chills | Mild | 21 | 0 | 25SEP2020 10:20 |
| | | 17OCT2020 21:45 | Headache | Mild | 22 | 1 | 25SEP2020 10:20 |
| | | 17OCT2020 21:45 | Fatigue | Mild | 22 | 1 | 25SEP2020 10:20 |
| | | 17OCT2020 21:45 | Arthralgia | Mild | 22 | 1 | 25SEP2020 10:20 |
| | | 17OCT2020 21:45 | Chills | Mild | 22 | 1 | 25SEP2020 10:20 |
| | 10364 | 26SEP2020 22:00 | Fatigue | Mild | 1 | | 25SEP2020 10:50 |
| | | 27SEP2020 22:00 | Fatigue | Mild | 2 | | 25SEP2020 10:50 |
| | | 28SEP2020 22:00 | Fatigue | Mild | 3 | | 25SEP2020 10:50 |
| | | 16OCT2020 21:00 | Headache | Mild | 21 | 0 | 25SEP2020 10:50 |
| | | 16OCT2020 21:00 | Fatigue | Mild | 21 | 0 | 25SEP2020 10:50 |
| | Program: Lsaf_sysR_1.sas (Page 90 of 92) | | | | | | |

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Older | 10365 | 23SEP2020 20:00 | Headache | Mild | 0 | | 23SEP2020 9:43 |
| | | 23SEP2020 20:00 | Fatigue | Mild | 0 | | 23SEP2020 9:43 |
| | | 24SEP2020 20:00 | Headache | Severe | 1 | | 23SEP2020 9:43 |
| | | 24SEP2020 20:00 | Fatigue | Mild | 1 | | 23SEP2020 9:43 |
| | | 24SEP2020 20:00 | Myalgia | Mild | 1 | | 23SEP2020 9:43 |
| | | 24SEP2020 20:00 | Malaise | Mild | 1 | | 23SEP2020 9:43 |
| | | 25SEP2020 20:00 | Fatigue | Mild | 2 | | 23SEP2020 9:43 |
| | | 25SEP2020 20:00 | Myalgia | Mild | 2 | | 23SEP2020 9:43 |
| | | 14OCT2020 21:00 | Nausea | Mild | 21 | 0 | 23SEP2020 9:43 |
| | | 14OCT2020 21:00 | Headache | Moderate | 21 | 0 | 23SEP2020 9:43 |
| | | 14OCT2020 21:00 | Fatigue | Moderate | 21 | 0 | 23SEP2020 9:43 |
| | | 14OCT2020 21:00 | Myalgia | Moderate | 21 | 0 | 23SEP2020 9:43 |
| | | 14OCT2020 21:00 | Chills | Moderate | 21 | 0 | 23SEP2020 9:43 |
| | | 14OCT2020 21:00 | Loss of Appetite | Mild | 21 | 0 | 23SEP2020 9:43 |
| | | 14OCT2020 21:00 | Malaise | Moderate | 21 | 0 | 23SEP2020 9:43 |
| | | 14OCT2020 21:00 | Fever | Mild | 21 | 0 | 23SEP2020 9:43 |
| | | 15OCT2020 21:00 | Headache | Mild | 22 | 1 | 23SEP2020 9:43 |
| | | 15OCT2020 21:00 | Fatigue | Moderate | 22 | 1 | 23SEP2020 9:43 |

Program: Lsaf_sysR_1.sas (Page 91 of 92)

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Listing 16.2.3-1.3-1: Listing of solicited systemic reactions - BNT162b1

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Older | 10365 | 15OCT2020 21:00 | Myalgia | Mild | 22 | 1 | 23SEP2020 9:43 |
| | | 15OCT2020 21:00 | Loss of Appetite | Mild | 22 | 1 | 23SEP2020 9:43 |
| | | 15OCT2020 21:00 | Malaise | Mild | 22 | 1 | 23SEP2020 9:43 |
| | | 16OCT2020 21:00 | Fatigue | Mild | 23 | 2 | 23SEP2020 9:43 |
| | | 18OCT2020 21:00 | Fatigue | Mild | 25 | 4 | 23SEP2020 9:43 |
| | | 19OCT2020 20:00 | Fatigue | Mild | 26 | 5 | 23SEP2020 9:43 |
| | | 19OCT2020 20:00 | Myalgia | Mild | 26 | 5 | 23SEP2020 9:43 |
| | | 20OCT2020 20:00 | Fatigue | Mild | 27 | 6 | 23SEP2020 9:43 |
| | 10366 | 14OCT2020 0:20 | Headache | Mild | 21 | 0 | 23SEP2020 10:13 |
| | | 14OCT2020 0:20 | Fatigue | Severe | 21 | 0 | 23SEP2020 10:13 |
| | | 14OCT2020 0:20 | Arthralgia | Mild | 21 | 0 | 23SEP2020 10:13 |
| | | 14OCT2020 0:20 | Chills | Mild | 21 | 0 | 23SEP2020 10:13 |
| | | 14OCT2020 0:20 | Fever | Mild | 21 | 0 | 23SEP2020 10:13 |
| | | 15OCT2020 21:20 | Headache | Mild | 22 | 1 | 23SEP2020 10:13 |
| | | 15OCT2020 21:20 | Fatigue | Severe | 22 | 1 | 23SEP2020 10:13 |
| 16OCT2020 21:00 | Fatigue | Moderate | 23 | 2 | 23SEP2020 10:13 | | |
| Program: Lsaf_sysR_1.sas (Page 92 of 92) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|--|--|-------------------------------|--|-----------------|---|
| 10015 1 µg Younger | headache Headache | 29APR2020 16:00 | 29APR2020 20:00 | 4.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Pain with movement at injection site Injection site pain | 29APR2020 16:00 | 30APR2020 7:00 | 15.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Tiredness Fatigue | 29APR2020 18:00 | 30APR2020 7:00 | 13.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Pain injection side Injection site pain | 20MAY2020 18:00 | 21MAY2020 7:00 | 13.0 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Headache Headache | 20MAY2020 20:00 | 21MAY2020 22:00 | 26.0 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10018 1 µg Younger | headache Headache | 29APR2020 14:30 | 29APR2020 17:00 | 2.5 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 1 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-------------------------------|--|-----------------|---|
| 10018 1 µg Younger | Discomfort with movement at injection site Injection site discomfort | 29APR2020 21:00 | 30APR2020 7:00 | 10.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Increased Lymphocytes Lymphocyte count increased | 27MAY2020 8:58 | 17JUN2020 8:13 | 503.3 8 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10025 1 µg Younger | Tiredness Fatigue | 05MAY2020 14:00 | 05MAY2020 22:00 | 8.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Shivering Chills | 05MAY2020 18:00 | 05MAY2020 20:00 | 2.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Injection site (pain, discomfort to touch) Injection site reaction | 26MAY2020 | 27MAY2020 | - 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Flue like symptoms (headache, myalgia, chills, tiredness) Influenza like illness | 26MAY2020 21:00 | 31MAY2020 8:30 | 107.5 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> | | | | | | | | | |
| <p>Program: Lsaf_AE_1.sas (Page 2 of 66)</p> | | | | | | | | | |

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Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10025 1 µg Younger | Tired, irritated eyes Asthenopia | 28MAY2020 17:00 | 31MAY2020 22:00 | 77.0 3 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Tired, irritated eyes Eye irritation | 28MAY2020 17:00 | 31MAY2020 22:00 | 77.0 3 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10033 1 µg Younger | Mild discomfort to touch at injection site Injection site discomfort | 05MAY2020 20:00 | 06MAY2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Flue like symptoms (headache, chills, myalgia, arthralgia, pyrexia, tiredness) Influenza like illness | 27MAY2020 2:00 | 28MAY2020 7:30 | 29.5 2 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Discomfort to touch at the injection side Injection site discomfort | 28MAY2020 | 29MAY2020 | - 3 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10036 1 µg Younger | Flue like symptoms (Pyrexia, Myalgia, Arthralgia, Chills) Influenza like illness | 29MAY2020 | 31MAY2020 | - 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 3 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|---------------------------------------|--|-------------------------------|-------------------------------------|-----------------|--|
| 10040 1 µg Younger | Injection site reactions (pain, tenderness, mild discomfort to touch) Injection site reaction | 08MAY2020 20:31 | 09MAY2020 8:28 | 12.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Tiredness Fatigue | 08MAY2020 20:32 | 10MAY2020 6:00 | 33.5 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | flu like symptoms (malaise, tiredness, myalgia, headache) Influenza like illness | 13MAY2020 | 14MAY2020 7:00 | - 6 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Loss of appetite Decreased appetite | 29MAY2020 | 03JUN2020 7:00 | - 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Burning sensation at injection site Injection site pain | 29MAY2020 9:00 | 29MAY2020 12:00 | 3.0 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Flu like symptoms (headache, myalgia, arthralgia, nausea, tiredness) Influenza like illness | 29MAY2020 12:37 | 12JUN2020 | - 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 4 of 66) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10040 1 µg Younger | Injection site reactions (pain, discomfort to touch, hardening, swelling) Injection site reaction | 30MAY2020 | 10JUN2020 20:00 | - 2 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Cervicobrachialgia Cervicobrachial syndrome | 12JUN2020 14:00 | 01AUG2020 6:00 | 1192.0 15 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Headache Headache | 12JUN2020 18:00 | 01AUG2020 6:00 | 1188.0 15 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10041 1 µg Younger | Injection site reactions (mild discomfort to touch, pain) Injection site reaction | 08MAY2020 15:07 | 10MAY2020 5:30 | 38.4 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Loose stool (2x) Diarrhoea | 08MAY2020 17:00 | 08MAY2020 21:00 | 4.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Intermittent Tiredness Fatigue | 09MAY2020 8:00 | 15MAY2020 7:00 | 143.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 5 of 66) | | | | | | | | | |

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Listing 16.2.3-1.5-1: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 10041 1 µg Younger | Gastrointestinal disorder Gastrointestinal disorder | 09MAY2020 18:20 | 09MAY2020 18:50 | 0.5 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Itching at head and back Pruritus | 12MAY2020 21:20 | 12MAY2020 | - 5 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Gastrointestinal disorder Gastrointestinal disorder | 13MAY2020 19:30 | 14MAY2020 0:30 | 5.0 6 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | flu like symptom (chills, malaise) Influenza like illness | 13MAY2020 21:00 | 13MAY2020 | - 6 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Pain right hand Pain in extremity | 14MAY2020 14:00 | 14MAY2020 21:00 | 7.0 7 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | headache cervico-occipital Headache | 14MAY2020 18:00 | 14MAY2020 20:30 | 2.5 7 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 6 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 10041 1 µg Younger | Paraesthesia left arm (injection site) due to myogelosis scapulae Injection site paraesthesia | 18MAY2020 7:50 | 08JUL2020 8:00 | 1224.2 11 | Dose Not Changed No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | reduction of power left arm due to myogelosis scapulae Myalgia | 18MAY2020 7:50 | 08JUL2020 8:00 | 1224.2 11 | Dose Not Changed No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Paraesthesia left arm (injection site) due to myogelosis scapulae Myosclerosis | 18MAY2020 7:50 | 08JUL2020 8:00 | 1224.2 11 | Dose Not Changed No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | reduction of power left arm due to myogelosis scapulae Muscle strength abnormal | 18MAY2020 7:50 | 08JUL2020 8:00 | 1224.2 11 | Dose Not Changed No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Headache Headache | 28MAY2020 18:30 | 28MAY2020 21:00 | 2.5 21 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Headache Headache | 29MAY2020 6:30 | 30MAY2020 12:00 | 29.5 1 | Dose Not Changed Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 7 of 66) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 10041 1 µg Younger | Flu like symptoms (Headache, arthralgia, myalgia, nausea, chills, tiredness) Influenza like illness | 29MAY2020 17:15 | 03JUN2020 | - 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Loss of appetite Decreased appetite | 29MAY2020 21:00 | 06JUN2020 12:00 | 183.0 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Injection site reactions (pain,discomfort to touch, hardening, swelling) Injection site reaction | 30MAY2020 | 01JUN2020 | - 2 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Dry mouth Dry mouth | 31MAY2020 1:30 | 07JUN2020 7:00 | 173.5 3 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Taste disorders Taste disorder | 31MAY2020 1:30 | 06JUN2020 12:00 | 154.5 3 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Massive tension at neck Muscle tightness | 04JUN2020 | 08JUL2020 8:00 | - 7 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 8 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10041 1 µg Younger | Headache Headache | 04JUN2020 4:00 | 11JUN2020 8:00 | 172.0 7 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Pain injection arm Injection site pain | 04JUN2020 6:00 | 08JUL2020 8:00 | 818.0 7 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Flu-like symptoms (sore throat, arthralgia, malaise) Influenza like illness | 25JUN2020 16:00 | 26JUN2020 8:00 | 16.0 28 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10042 1 µg Younger | Tiredness Fatigue | 08MAY2020 9:30 | 09MAY2020 5:30 | 20.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Vasovagal immediate post-injection reaction Presyncope | 29MAY2020 10:01 | 29MAY2020 10:02 | 0.0 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10045 1 µg Younger | Tiredness Fatigue | 05MAY2020 19:00 | 06MAY2020 6:00 | 11.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 9 of 66)</p> | | | | | | | | | |

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-------------------------------|--|-----------------|---|
| 10048 1 µg Younger | Tiredness Fatigue | 08MAY2020 20:06 | 09MAY2020 6:30 | 10.4 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10052 1 µg Younger | Tenderness, mild discomfort to touch at injection site Injection site pain | 08MAY2020 19:00 | 09MAY2020 7:00 | 12.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Tenderness, mild discomfort to touch at injection site Injection site discomfort | 08MAY2020 19:00 | 09MAY2020 7:00 | 12.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Headache Headache | 08MAY2020 22:00 | 09MAY2020 1:00 | 3.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Headache Headache | 13MAY2020 18:10 | 13MAY2020 23:00 | 4.8 6 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Tiredness Fatigue | 30MAY2020 8:00 | 31MAY2020 7:00 | 23.0 2 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 10 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10052 1 µg Younger | Injection site reactions (pain, discomfort with movement) Injection site reaction | 02JUN2020 9:00 | 02JUN2020 20:00 | 11.0 5 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Headache Headache | 02JUN2020 19:00 | 02JUN2020 23:30 | 4.5 5 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | regular tachycardia (stress related) Tachycardia | 19JUN2020 9:00 | 25JUN2020 8:57 | 144.0 22 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 10212 3 µg Younger | Diarrhea Diarrhoea | 24JUL2020 15:00 | 24JUL2020 18:00 | 3.0 3 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 10225 3 µg Younger | Headache Headache | 30JUL2020 22:00 | 01AUG2020 6:00 | 32.0 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | No No | No No |
| 10001 10 µg Younger | mild discomfort to touch at injection site Injection site discomfort | 15MAY2020 17:00 | 15MAY2020 21:00 | 4.0 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 11 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10003 10 µg Younger | headache Headache | 28APR2020 11:33 | 28APR2020 16:00 | 4.5 1 | Dose Not Changed Yes | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Injection site reactions (mild discomfort to touch, pain) Injection site reaction | 28APR2020 22:00 | 30APR2020 6:00 | 32.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Headache Headache | 19MAY2020 10:30 | 20MAY2020 7:00 | 20.5 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Injection site reactions (discomfort with movement, tenderness) Injection site reaction | 19MAY2020 11:30 | 27MAY2020 7:00 | 187.5 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | headache Headache | 29MAY2020 20:00 | 29MAY2020 23:45 | 3.8 11 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10004 10 µg Younger | Tenderness at injections site Injection site pain | 24APR2020 18:00 | 25APR2020 21:00 | 27.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 12 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|---------------------------------------|--|-------------------------------|-------------------------------------|-----------------|--|
| 10004 10 µg Younger | Cough Cough | 25APR2020 10:00 | 26APR2020 14:00 | 28.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Sore throat Oropharyngeal pain | 25APR2020 10:00 | 26APR2020 14:00 | 28.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Loose stool (3x) Diarrhoea | 25APR2020 21:00 | 26APR2020 21:30 | 24.5 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | headache Headache | 15MAY2020 16:00 | 17MAY2020 7:00 | 39.0 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | flu like symptoms Influenza like illness | 15MAY2020 22:00 | 18MAY2020 7:00 | 57.0 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Injection site reactions (discomfort with movement, pain) Injection site reaction | 15MAY2020 23:00 | 19MAY2020 7:00 | 80.0 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 13 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-------------------------------|--|-----------------|---|
| 10005 10 µg Younger | Tiredness Fatigue | 24APR2020 13:00 | 25APR2020 19:30 | 30.5 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Headache Headache | 24APR2020 13:45 | 24APR2020 21:15 | 7.5 1 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Tenderness at injection site Injection site pain | 24APR2020 17:15 | 25APR2020 7:00 | 13.8 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Discomfort with movement at injection site Injection site discomfort | 25APR2020 7:00 | 25APR2020 19:30 | 12.5 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Headache Headache | 25APR2020 10:00 | 25APR2020 22:00 | 12.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Tiredness Fatigue | 28APR2020 | 28APR2020 | - 5 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 14 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10005 10 µg Younger | Headache Headache | 12MAY2020 18:30 | 13MAY2020 15:00 | 20.5 19 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Injection site reactions (mild discomfort to touch, pain) Injection site reaction | 15MAY2020 16:00 | 17MAY2020 7:00 | 39.0 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | flu like symptoms (chills, malaise, myalgia, arthralgia, intermittent headache, tiredness) Influenza like illness | 15MAY2020 18:00 | 17MAY2020 12:00 | 42.0 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Headache Headache | 02JUN2020 18:00 | 03JUN2020 9:30 | 15.5 19 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10006 10 µg Younger | Headache Headache | 29APR2020 | 30APR2020 | - 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Tiredness Fatigue | 29APR2020 6:00 | 30APR2020 | - 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 15 of 66) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 10006 10 µg Younger | elevated body temperature Body temperature increased | 29APR2020 8:12 | 29APR2020 22:00 | 13.8 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | redness of injection site > 2,5 cm Injection site erythema | 29APR2020 8:30 | 29APR2020 22:00 | 13.5 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Hyperpigmentation of skin at injection site (approx. 3,5 cm) Injection site discolouration | 05MAY2020 8:43 | 07MAY2020 7:00 | 46.3 8 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Gingivitis Gingivitis | 12MAY2020 17:00 | 16MAY2020 19:00 | 98.0 15 | Dose Not Changed Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | intermittent chest pain due to muscular tension Musculoskeletal chest pain | 14MAY2020 | 16MAY2020 9:30 | - 17 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | flu-like symptoms Influenza like illness | 19MAY2020 20:00 | 20MAY2020 18:00 | 22.0 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 16 of 66) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10006 10 µg Younger | mild discomfort to touch at injection site Injection site discomfort | 19MAY2020 20:00 | 21MAY2020 7:00 | 35.0 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Presyncope Presyncope | 20MAY2020 10:00 | 20MAY2020 10:01 | 0.0 2 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10007 10 µg Younger | Headache Headache | 23APR2020 8:20 | 24APR2020 16:00 | 31.7 1 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | No No | No No |
| | Pain at injection site Injection site pain | 23APR2020 18:00 | 29APR2020 7:00 | 133.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | intermittent heat flushes Hot flush | 24APR2020 22:00 | 25APR2020 9:00 | 11.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | intermittent tiredness Fatigue | 25APR2020 7:00 | 27APR2020 | - 3 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 17 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10007 10 µg Younger | headache intermittent Headache | 25APR2020 8:00 | 28APR2020 18:00 | 82.0 3 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | headache Headache | 13MAY2020 16:00 | 13MAY2020 19:00 | 3.0 21 | Dose Not Changed Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Injection site reactions (discomfort with movement, pain, swelling) Injection site reaction | 14MAY2020 14:30 | 19MAY2020 7:00 | 112.5 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | flu-like symptoms (incl. intermitt. headache) Influenza like illness | 14MAY2020 18:00 | 19MAY2020 7:00 | 109.0 1 | Not Applicable Yes | Related Recovered/Resolved | Mild No | Yes No | No No |
| | dizziness Dizziness | 22MAY2020 6:30 | 22MAY2020 13:00 | 6.5 9 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | headache Headache | 22MAY2020 6:30 | 22MAY2020 18:00 | 11.5 9 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 18 of 66) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 10008 10 µg Younger | occipital headache Headache | 28APR2020 14:00 | 28APR2020 17:00 | 3.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Injection site reactions (mild discomfort to touch, mild discomfort with movement) Injection site reaction | 28APR2020 18:00 | 30APR2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Tiredness Fatigue | 29APR2020 | 30APR2020 | - 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | flu-like symptoms Influenza like illness | 19MAY2020 18:00 | 20MAY2020 17:00 | 23.0 1 | Not Applicable Yes | Related Recovered/Resolved | Severe No | Yes No | No Yes |
| | mild discomfort to touch at injection site Injection site discomfort | 19MAY2020 18:00 | 22MAY2020 7:00 | 61.0 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Rhinitis allergica Rhinitis allergic | 27MAY2020 11:00 | 07JUN2020 10:00 | 263.0 9 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 19 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10008 10 µg Younger | Pollen allergy Seasonal allergy | 10JUN2020 10:00 | 14JUN2020 12:00 | 98.0 23 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10009 10 µg Younger | Tiredness Fatigue | 28APR2020 | 28APR2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Injection site reactions (mild pain, mild discomfort to touch) Injection site reaction | 28APR2020 20:00 | 01MAY2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | flu like symptoms Influenza like illness | 19MAY2020 21:00 | 20MAY2020 22:00 | 25.0 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Injection site reactions (mild discomfort to touch, pain) Injection site reaction | 19MAY2020 21:00 | 20MAY2020 22:00 | 25.0 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10010 10 µg Younger | Tiredness Fatigue | 24APR2020 | 07MAY2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 20 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10010 10 µg Younger | Flu-like symptoms Influenza like illness | 25APR2020 10:10 | 07MAY2020 | - 2 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Injection site reactions (pain, tenderness, discomfort with movement) Injection site reaction | 25APR2020 13:00 | 03MAY2020 7:00 | 186.0 2 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Loose stool Diarrhoea | 25APR2020 21:00 | 26APR2020 20:00 | 23.0 2 | Dose Not Changed No | Related Recovering/Resolving | Moderate No | Yes No | No No |
| | Loose stool Diarrhoea | 26APR2020 20:00 | 27APR2020 21:00 | 25.0 3 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | stress dyspnea Dyspnoea exertional | 27APR2020 | 07MAY2020 | - 4 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Cough Cough | 06MAY2020 7:00 | 07MAY2020 | - 13 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 21 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10010 10 µg Younger | Verruca -> operation in local anesthesia Papilloma excision | 08MAY2020 | 08MAY2020 | - 15 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Malaise Malaise | 12MAY2020 | 16MAY2020 19:00 | - 19 | Drug Withdrawn Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | myalgia (both arms and legs) Myalgia | 12MAY2020 | 16MAY2020 19:00 | - 19 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | myalgia (both arms and legs) Myalgia | 12MAY2020 | 16MAY2020 19:00 | - 19 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Shivering Chills | 12MAY2020 22:00 | 13MAY2020 | - 19 | Dose Not Changed No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Intermittent Fever up to 39,3 degree C Pyrexia | 12MAY2020 22:00 | 14MAY2020 19:00 | 45.0 19 | Dose Not Changed Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 22 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|-------------------|---------------------------------------|--|-------------------------------|-------------------------------------|-----------------|--|
| 10011 10 µg Younger | Injection site reactions (tenderness, pain) Injection site reaction | 24APR2020 19:15 | 27APR2020 6:05 | 58.8 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Genital herpes Genital herpes | 26APR2020 | 07MAY2020 | - 3 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Injection site reactions (mild discomfort to touch, pain) Injection site reaction | 15MAY2020 | 17MAY2020 7:00 | - 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10017 10 µg Younger | mild discomfort with movement at injection site Injection site discomfort | 28APR2020 12:30 | 30APR2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | head pressure Head discomfort | 28APR2020 13:30 | 29APR2020 6:45 | 17.3 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | mild pain at injection site Injection site pain | 19MAY2020 12:00 | 20MAY2020 7:00 | 19.0 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 23 of 66) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10017 10 µg Younger | headache Headache | 19MAY2020 20:00 | 20MAY2020 8:00 | 12.0 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | muscle pain in lumbar region Myalgia | 20MAY2020 6:30 | 21MAY2020 8:00 | 25.5 2 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10019 10 µg Younger | flu-like symptoms Influenza like illness | 20MAY2020 0:00 | 21MAY2020 7:00 | 31.0 2 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Intermittent headache Headache | 21MAY2020 8:00 | 28MAY2020 0:00 | 160.0 3 | Not Applicable Yes | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10151 20 µg Younger | Abdominal pain (lower abdomen) Abdominal pain lower | 17JUL2020 13:00 | 18JUL2020 21:00 | 32.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10171 20 µg Younger | Conjunctivitis right eye Conjunctivitis | 06AUG2020 12:00 | 08AUG2020 12:00 | 48.0 1 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 24 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10171 20 µg Younger | Nasal congestion Nasal congestion | 06AUG2020 12:00 | 08AUG2020 12:00 | 48.0 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Swollen lymph node left axilla Lymphadenopathy | 09AUG2020 12:00 | 11AUG2020 12:00 | 48.0 4 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10172 20 µg Younger | Paresthesia of both arms Paraesthesia | 18JUL2020 6:30 | 18JUL2020 9:30 | 3.0 3 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Headache Headache | 27JUL2020 12:00 | 27JUL2020 20:00 | 8.0 12 | Dose Not Changed No | Not Related Recovered/Resolved | Severe No | Yes No | No No |
| | Headache Headache | 06AUG2020 8:00 | 07AUG2020 11:30 | 27.5 1 | Dose Not Changed Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Headache Headache | 01SEP2020 9:00 | 01SEP2020 19:00 | 10.0 27 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 25 of 66)</p> | | | | | | | | | |

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 10173 20 µg Younger | Throat pain with coarse voice Dysphonia | 18JUL2020 9:30 | 20JUL2020 8:10 | 46.7 3 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Throat pain with coarse voice Oropharyngeal pain | 18JUL2020 9:30 | 20JUL2020 8:10 | 46.7 3 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10179 20 µg Younger | Depression Depression | 13AUG2020 7:00 | | - 8 | Not Applicable Yes | Not Related | Severe No | Yes No | No No |
| | Sleeping disorder Sleep disorder | 13AUG2020 20:00 | 02SEP2020 20:00 | 480.0 8 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10197 20 µg Younger | Gingival pain diffuse Gingival pain | 17JUL2020 20:30 | 19JUL2020 11:00 | 38.5 2 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Dizziness Dizziness | 06AUG2020 20:30 | 08AUG2020 20:00 | 47.5 1 | Not Applicable No | Related Recovered/Resolved | Severe No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 26 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|--|--|-------------------------------|--|-----------------|---|
| 10197 20 µg Younger | Hallucinations Hallucination | 06AUG2020 20:30 | 08AUG2020 20:00 | 47.5 1 | Not Applicable No | Related Recovered/Resolved | Severe No | Yes No | No No |
| | Hypersensitivity to light (eyes) Photophobia | 07AUG2020 7:30 | 09AUG2020 10:00 | 50.5 2 | Not Applicable No | Related Recovered/Resolved | Severe No | Yes No | No No |
| | thoracic pain (musculoskeletal) Musculoskeletal chest pain | 07AUG2020 7:30 | 12AUG2020 23:00 | 135.5 2 | Not Applicable No | Related Recovered/Resolved | Severe No | Yes No | No No |
| 10016 30 µg Younger | Flu-like symptoms (headache, dizziness, nausea, tiredness, pyrexia) Influenza like illness | 30APR2020 0:00 | 30APR2020 7:58 | 8.0 2 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Injection site reactions (pain discomfort with movement) Injection site reaction | 30APR2020 0:00 | 01MAY2020 7:30 | 31.5 2 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Headache Headache | 30APR2020 4:00 | 03MAY2020 0:00 | 68.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. | | | | | | | | | |
| Program: Lsaf_AE_1.sas (Page 27 of 66) | | | | | | | | | |

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Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10016 30 µg Younger | Discomfort with movement at injection site Injection site discomfort | 20MAY2020 11:31 | 22MAY2020 21:00 | 57.5 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Flue like Symptoms (ear pain, pyrexia, headache, chills) Influenza like illness | 20MAY2020 17:00 | 22MAY2020 7:00 | 38.0 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10020 30 µg Younger | Pain in lumbar region Back pain | 20MAY2020 | 22MAY2020 7:00 | - 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Lumbalgia Back pain | 13JUN2020 10:00 | 17JUN2020 14:00 | 100.0 25 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10021 30 µg Younger | Tiredness Fatigue | 05MAY2020 10:00 | 06MAY2020 6:00 | 20.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Headache Headache | 05MAY2020 18:00 | 06MAY2020 6:00 | 12.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 28 of 66) | | | | | | | | | |

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Listing 16.2.3-1.5-1: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|---------------------------------------|--|-------------------------------|-------------------------------------|-----------------|--|
| 10021 30 µg Younger | Injection site reactions (mild pain, mild tenderness to touch) Injection site reaction | 05MAY2020 18:30 | 07MAY2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Flu like symptoms (shivering, malaise) Influenza like illness | 06MAY2020 1:00 | 06MAY2020 6:00 | 5.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Mild tenderness to touch at injection site Injection site pain | 10MAY2020 | 11MAY2020 | - 6 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Flu-like symptoms Influenza like illness | 26MAY2020 15:00 | 29MAY2020 17:00 | 74.0 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Injection site reactions (pain, discomfort with movement) Injection site reaction | 26MAY2020 15:00 | 29MAY2020 9:00 | 66.0 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10028 30 µg Younger | Headache Headache | 07MAY2020 15:00 | 07MAY2020 22:00 | 7.0 1 | Dose Not Changed Yes | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 29 of 66)</p> | | | | | | | | | |

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Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-------------------------------|--|-----------------|---|
| 10028 30 µg Younger | Injection site reactions (pain, tenderness, mild discomfort to touch, redness 1,5 cm) Injection site reaction | 07MAY2020 21:27 | 11MAY2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Hyperpigmentation of the skin at injection site Injection site discolouration | 14MAY2020 8:12 | 21MAY2020 7:00 | 166.8 8 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Injection site reactions (pain, tenderness, mild discomfort to touch, itching) Injection site reaction | 28MAY2020 9:20 | 30MAY2020 7:00 | 45.7 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Headache Headache | 28MAY2020 21:00 | 28MAY2020 | - 1 | Not Applicable Yes | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Flue like symptoms (incl. headache) Influenza like illness | 29MAY2020 3:00 | 29MAY2020 21:00 | 18.0 2 | Not Applicable Yes | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10031 30 µg Younger | Injection site reactions (pain, discomfort with movement) Injection site reaction | 07MAY2020 12:00 | 10MAY2020 | - 1 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 30 of 66)</p> | | | | | | | | | |

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Listing 16.2.3-1.5-1: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 10031 30 µg Younger | flu-like symptoms (chills, malaise, loss of appetite, tiredness, headache, pyrexia) Influenza like illness | 07MAY2020 20:00 | 09MAY2020 6:00 | 34.0 1 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Increased CRP C-reactive protein increased | 09MAY2020 9:13 | 14MAY2020 8:15 | 119.0 3 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Flu like symptoms Influenza like illness | 28MAY2020 19:00 | 31MAY2020 14:00 | 67.0 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Injection site reactions (pain, discomfort with movement) Injection site reaction | 28MAY2020 19:00 | 01JUN2020 7:00 | 84.0 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Headache Headache | 29MAY2020 0:00 | 29MAY2020 23:00 | 23.0 2 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Rhinitis Rhinitis | 09JUN2020 7:00 | 11JUN2020 7:00 | 48.0 13 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 31 of 66)</p> | | | | | | | | | |

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Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10031 30 µg Younger | Pain right elbow Arthralgia | 13JUN2020 15:00 | 18JUN2020 15:00 | 120.0 17 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10032 30 µg Younger | Tiredness Fatigue | 05MAY2020 6:00 | 07MAY2020 6:00 | 48.0 1 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | No No | No No |
| | Headache Headache | 05MAY2020 15:00 | 06MAY2020 6:00 | 15.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Light tenderness + discomfort to touch at injection site Injection site pain | 05MAY2020 18:00 | 07MAY2020 7:00 | 37.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Light tenderness + discomfort to touch at injection site Injection site discomfort | 05MAY2020 18:00 | 07MAY2020 7:00 | 37.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | weariness Fatigue | 06MAY2020 12:00 | 07MAY2020 7:00 | 19.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 32 of 66) | | | | | | | | | |

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Listing 16.2.3-1.5-1: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|-------------------|---------------------------------------|--|-------------------------------|-------------------------------------|-----------------|--|
| 10032 30 µg Younger | loss of appetite Decreased appetite | 06MAY2020 12:00 | 07MAY2020 7:00 | 19.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | pain at injection site Injection site pain | 26MAY2020 11:30 | 28MAY2020 7:00 | 43.5 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Headache Headache | 26MAY2020 16:06 | 28MAY2020 7:00 | 38.9 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Discomfort to touch at injection site Injection site discomfort | 26MAY2020 16:06 | 28MAY2020 7:00 | 38.9 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Flu-like symptoms (arthralgia, myalgia, loss of appetite, malaise + tiredness Influenza like illness | 27MAY2020 7:00 | 28MAY2020 7:00 | 24.0 2 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10034 30 µg Younger | Flu-like symptoms (headache, dizziness, tiredness, weariness, shivering) Influenza like illness | 05MAY2020 21:30 | 07MAY2020 9:00 | 35.5 1 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 33 of 66)</p> | | | | | | | | | |

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Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-------------------------------|--|-----------------|---|
| 10034 30 µg Younger | local muscle pain injection arm Injection site pain | 05MAY2020 21:30 | 11MAY2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Injection site reactions (mild discomfort to touch, discomfort with movement, redness, swelling) Injection site reaction | 06MAY2020 7:00 | 12MAY2020 7:00 | 144.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Tiredness Fatigue | 08MAY2020 12:00 | 08MAY2020 18:00 | 6.0 4 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Haematoma at injection site Injection site haematoma | 12MAY2020 7:00 | 24MAY2020 7:00 | 288.0 8 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Injection site reactions (mild discomfort to touch, pain, discomfort with movement) Injection site reaction | 26MAY2020 14:30 | 29MAY2020 7:30 | 65.0 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Flu-like symptom (myalgia, arthralgia, chills, malaise, tiredness, pyrexia, headache) Influenza like illness | 26MAY2020 19:30 | 28MAY2020 7:30 | 36.0 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 34 of 66)</p> | | | | | | | | | |

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Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-------------------------------|--|-----------------|---|
| 10037 30 µg Younger | Injection site reactions (mild discomfort to touch, pain) Injection site reaction | 05MAY2020 12:00 | 07MAY2020 21:00 | 57.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Headache Headache | 06MAY2020 8:00 | 07MAY2020 21:00 | 37.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Tiredness Fatigue | 07MAY2020 8:00 | 07MAY2020 21:00 | 13.0 3 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Weariness Fatigue | 07MAY2020 8:00 | 07MAY2020 21:00 | 13.0 3 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Tiredness Fatigue | 10MAY2020 8:00 | 10MAY2020 21:00 | 13.0 6 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Injection site reactions (mild discomfort to touch, pain, discomfort with movement) Injection site reaction | 26MAY2020 14:30 | 30MAY2020 7:30 | 89.0 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 35 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 10037 30 µg Younger | Flu-like symptoms Influenza like illness | 26MAY2020 17:00 | 01JUN2020 18:00 | 145.0 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Headache Headache | 17JUN2020 7:00 | 18JUN2020 7:00 | 24.0 23 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Headache Headache | 21JUN2020 12:00 | 21JUN2020 21:00 | 9.0 27 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 10038 30 µg Younger | Injection site reactions (pain, tenderness, discomfort with movement, muscle pain) Injection site reaction | 07MAY2020 21:00 | 08MAY2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Discomfort to touch at injection site Injection site discomfort | 28MAY2020 15:00 | 28MAY2020 17:00 | 2.0 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10039 30 µg Younger | Flu-like Symptoms (headache, elevated body temperature) Influenza like illness | 07MAY2020 18:00 | 09MAY2020 | - 1 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 36 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|-------------------|--|--|-------------------------------|--|-----------------|---|
| 10039 30 µg Younger | Injection site reactions (pain, tenderness, discomfort with movement) Injection site reaction | 07MAY2020 22:00 | 10MAY2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Flu like symptoms (incl. dizziness, headache) Influenza like illness | 28MAY2020 20:00 | 30MAY2020 8:00 | 36.0 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Injection site reactions (pain, tenderness, mild discomfort to touch) Injection site reaction | 28MAY2020 22:00 | 31MAY2020 7:00 | 57.0 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10043 30 µg Younger | Headache Headache | 07MAY2020 19:00 | 13MAY2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Injection site reactions (pain, tenderness, discomfort with movement, redness 4 cm) Injection site reaction | 07MAY2020 20:00 | 13MAY2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Dizziness Dizziness | 08MAY2020 20:00 | 09MAY2020 0:00 | 4.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 37 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10043 30 µg Younger | Hyperpigmentation at injection site (4cm) Injection site discolouration | 14MAY2020 9:40 | 17MAY2020 7:00 | 69.3 8 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Headache (due to muscle tension of the neck) Headache | 15MAY2020 | 01JUN2020 16:00 | - 9 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Headache (due to muscle tension of the neck) Muscle tightness | 15MAY2020 | 01JUN2020 16:00 | - 9 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Injection site reactions (discomfort with movement, pain, mild discomfort to touch) Injection site reaction | 28MAY2020 16:00 | 01JUN2020 7:00 | 87.0 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Flu-like symptoms Influenza like illness | 29MAY2020 8:00 | 29MAY2020 18:00 | 10.0 2 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10047 30 µg Younger | Injection site reactions (pain, tenderness, discomfort with movement) Injection site reaction | 07MAY2020 | 11MAY2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 38 of 66) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|---------------------------------------|--|-------------------------------|-------------------------------------|-----------------|--|
| 10047 30 µg Younger | Headache intermittent Headache | 07MAY2020 17:30 | 11MAY2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Flu-like Symptoms Influenza like illness | 07MAY2020 17:30 | 09MAY2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Loose Stool (2x) Diarrhoea | 07MAY2020 18:00 | 07MAY2020 20:00 | 2.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Tiredness Fatigue | 09MAY2020 | 11MAY2020 | - 3 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Flu like symptoms Influenza like illness | 29MAY2020 0:00 | 01JUN2020 0:30 | 72.5 2 | Not Applicable Yes | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Injection site reactions (pain, tenderness, mild discomfort to touch) Injection site reaction | 29MAY2020 0:00 | 01JUN2020 0:30 | 72.5 2 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 39 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-------------------------------|--|-----------------|---|
| 10047 30 µg Younger | Pityriasis rosea Pityriasis rosea | 08JUN2020 18:00 | 17JUL2020 0:00 | 918.0 12 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10049 50 µg Younger | Injection site reactions (mild discomfort to touch, discomfort with movement, paraesthesia) Injection site reaction | 12MAY2020 14:00 | 14MAY2020 7:00 | 41.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Flu-like symptoms (Tiredness, malaise, feeling feverish, headache) Influenza like illness | 12MAY2020 14:30 | 13MAY2020 14:30 | 24.0 1 | Dose Not Changed Yes | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Pyrexia Pyrexia | 13MAY2020 13:00 | 14MAY2020 13:45 | 24.8 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Neck-pain left side Neck pain | 15MAY2020 13:00 | 15MAY2020 17:00 | 4.0 4 | Dose Not Changed Yes | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Headache Headache | 02JUN2020 23:00 | 05JUN2020 9:00 | 58.0 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 40 of 66)</p> | | | | | | | | | |

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Listing 16.2.3-1.5-1: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 10049 50 µg Younger | Flu-like symptoms Influenza like illness | 02JUN2020 23:00 | 05JUN2020 9:00 | 58.0 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Injection site reactions (pain, tenderness, mild discomfort, induration, swelling) Injection site reaction | 02JUN2020 23:00 | 04JUN2020 9:00 | 34.0 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Loss of appetite Decreased appetite | 02JUN2020 23:00 | 05JUN2020 7:00 | 56.0 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Herpes simplex infection, lips and left nose nostril Oral herpes | 04JUN2020 17:00 | 13JUN2020 15:00 | 214.0 3 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Herpes simplex infection, lips and left nose nostril Nasal herpes | 04JUN2020 17:00 | 13JUN2020 15:00 | 214.0 3 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Diarrhea Diarrhoea | 20JUN2020 20:00 | 21JUN2020 9:00 | 13.0 19 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 41 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 10050 50 µg Younger | Injection site reactions (itching, pain, discomfort with movement, intermittent swelling, redness 5 cm) Injection site reaction | 15MAY2020 11:45 | 21MAY2020 20:00 | 152.3 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Headache Headache | 15MAY2020 14:15 | 20MAY2020 20:00 | 125.8 1 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Flu-like symptoms (loss of appetite, malaise, tiredness) Influenza like illness | 15MAY2020 18:00 | 21MAY2020 20:00 | 146.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | chills Chills | 16MAY2020 3:30 | 16MAY2020 5:00 | 1.5 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | menstrual pain Dysmenorrhoea | 23MAY2020 17:00 | 23MAY2020 18:00 | 1.0 9 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 10053 50 µg Younger | Hypotension during blood draw for CMI Blood pressure decreased | 12MAY2020 8:15 | 12MAY2020 8:29 | 0.2 1 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | No No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 42 of 66) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10053 50 µg Younger | Tiredness Fatigue | 12MAY2020 8:30 | 13MAY2020 7:15 | 22.8 1 | Not Applicable No | Not Related Recovered/Resolved | Mild No | No No | No No |
| | Flu-like symptoms Influenza like illness | 12MAY2020 20:00 | 14MAY2020 8:45 | 36.8 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Injection site reactions (pain, mild discomfort to touch) Injection site reaction | 12MAY2020 20:00 | 16MAY2020 7:00 | 83.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Pyrexia Pyrexia | 13MAY2020 8:16 | 14MAY2020 20:00 | 35.7 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Injection site reactions (mild discomfort to touch, pain) Injection site reaction | 02JUN2020 11:45 | 04JUN2020 7:00 | 43.3 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Flu-like Symptoms Influenza like illness | 02JUN2020 20:00 | 04JUN2020 7:00 | 35.0 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 43 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|---------------------------------------|--|-------------------------------|-------------------------------------|-----------------|--|
| 10055 50 µg Younger | Tiredness Fatigue | 13MAY2020 11:30 | 14MAY2020 6:00 | 18.5 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Headache Headache | 13MAY2020 13:00 | 15MAY2020 14:00 | 49.0 1 | Dose Not Changed Yes | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Arthralgia in both knees Arthralgia | 14MAY2020 6:00 | 16MAY2020 | - 2 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Injection site reactions (mild discomfort to touch, pain) Injection site reaction | 14MAY2020 6:00 | 16MAY2020 | - 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Pain in joints and muscles, lower body half Arthralgia | 03JUN2020 17:00 | 04JUN2020 20:00 | 27.0 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Injection site reactions (pain, mild discomfort to touch, discomfort) Injection site reaction | 03JUN2020 17:00 | 05JUN2020 | - 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 44 of 66) | | | | | | | | | |

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|--|--|-------------------------------|--|-----------------|---|
| 10055 50 µg Younger | Pain in joints and muscles, lower body half Myalgia | 03JUN2020 17:00 | 04JUN2020 20:00 | 27.0 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Loss of appetite Decreased appetite | 03JUN2020 17:00 | 04JUN2020 20:00 | 27.0 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Haematoma at injection side Injection site haematoma | 04JUN2020 11:00 | 13JUN2020 16:00 | 221.0 2 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10056 50 µg Younger | Flu-like symptoms (nausea, headache, tiredness, malaise, chills, pyrexia intermitt., arthralgia) Influenza like illness | 13MAY2020 20:00 | 17MAY2020 23:00 | 99.0 1 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Injection site reactions (pain, discomfort with movement) Injection site reaction | 14MAY2020 0:00 | 15MAY2020 13:00 | 37.0 2 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Loss of appetite Decreased appetite | 14MAY2020 7:00 | 14MAY2020 23:00 | 16.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 45 of 66) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-------------------------------|--|-----------------|---|
| 10056 50 µg Younger | Cough Cough | 15MAY2020 0:00 | 19MAY2020 0:00 | 96.0 3 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Flu like symptoms Influenza like illness | 03JUN2020 16:00 | 07JUN2020 8:00 | 88.0 1 | Not Applicable Yes | Related Recovered/Resolved | Severe No | Yes No | No Yes |
| | Injection site reactions (pain, tenderness, mild discomfort to touch) Injection site reaction | 03JUN2020 18:00 | 07JUN2020 8:00 | 86.0 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10057 50 µg Younger | Flu-like symptoms Influenza like illness | 15MAY2020 19:30 | 17MAY2020 18:00 | 46.5 1 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Injection site reactions (pain, sensitivity at touch) Injection site reaction | 15MAY2020 19:30 | 17MAY2020 8:00 | 36.5 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Flu-like symptoms (Headache, myalgia, arthralgia, chills, fatigue, malaise) Influenza like illness | 05JUN2020 | 08JUN2020 | - 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 46 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10057 50 µg Younger | Injection site reactions (pain that interferes with activity, significant discomfort at rest) Injection site reaction | 05JUN2020 20:38 | 09JUN2020 14:00 | 89.4 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Tinea pedis of right foot Tinea pedis | 06JUN2020 | 02JUL2020 20:00 | - 2 | Not Applicable Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Inguinal mycosis Fungal infection | 13JUN2020 19:00 | 19JUN2020 20:00 | 145.0 9 | Not Applicable Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Dysphagia Dysphagia | 14JUN2020 19:00 | 17JUN2020 19:00 | 72.0 10 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 10059 50 µg Younger | Injection site reactions (pain, discomfort with movement) Injection site reaction | 13MAY2020 16:50 | 15MAY2020 20:00 | 51.2 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Flu-like symptoms (nausea, chills, malaise, headache, pyrexia 2x, arthralgia) Influenza like illness | 13MAY2020 17:30 | 18MAY2020 9:00 | 111.5 1 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 47 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

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Listing 16.2.3-1.5-1: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|---------------------------------------|--|-------------------------------|-------------------------------------|-----------------|--|
| 10059 50 µg Younger | Vomiting Vomiting | 13MAY2020 22:40 | 13MAY2020 22:40 | 0.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Injection site reactions (pain, tenderness) Injection site reaction | 03JUN2020 11:50 | 11JUN2020 8:00 | 188.2 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Flu like symptoms (headache, fever, malaise, chills, burning eyes) Influenza like illness | 03JUN2020 17:30 | 07JUN2020 14:00 | 92.5 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Vomiting Vomiting | 03JUN2020 23:45 | 03JUN2020 23:45 | 0.0 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10060 50 µg Younger | Flu like symptoms(chills, tiredness, malaise) Influenza like illness | 14MAY2020 18:00 | 15MAY2020 8:00 | 14.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Pain to touch at injection site Injection site pain | 14MAY2020 18:30 | 15MAY2020 8:00 | 13.5 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 48 of 66) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-------------------------------|--|-----------------|---|
| 10060 50 µg Younger | Headache Headache | 14MAY2020 19:00 | 14MAY2020 21:00 | 2.0 2 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Injection site reactions (pain, tenderness) Injection site reaction | 04JUN2020 6:00 | 04JUN2020 19:00 | 13.0 2 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Flu like symptoms Influenza like illness | 04JUN2020 14:30 | 04JUN2020 18:30 | 4.0 2 | Not Applicable Yes | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10067 50 µg Younger | Flu-like symptoms (headache, fatigue, malaise, shivering) Influenza like illness | 15MAY2020 22:00 | 16MAY2020 22:00 | 24.0 1 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Mild discomfort to touch at injection site Injection site discomfort | 15MAY2020 22:00 | 16MAY2020 7:00 | 9.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Flu-like symptoms (Headache, myalgia, chills, fatigue) Influenza like illness | 05JUN2020 19:00 | 07JUN2020 | - 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 49 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-------------------------------|--|-----------------|---|
| 10067 50 µg Younger | Injection site reactions (pain, discomfort with movement) Injection site reaction | 05JUN2020 22:00 | 07JUN2020 | - 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10068 50 µg Younger | Injection site reactions (mild discomfort to touch, discomfort with movement, intermittent muscle pain in the arm, redness 3-3,5cm, swelling 3cm) Injection site reaction | 15MAY2020 16:19 | 20MAY2020 23:30 | 127.2 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Elevated CRP C-reactive protein increased | 16MAY2020 8:40 | 22MAY2020 9:29 | 144.8 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Headache Headache | 16MAY2020 10:30 | 17MAY2020 23:00 | 36.5 2 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Flu like symptoms Influenza like illness | 16MAY2020 17:00 | 17MAY2020 11:00 | 18.0 2 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Flu-like symptoms (Headache, myalgia, arthralgia, nausea, chills, loss of appetite, malaise, fatigue) Influenza like illness | 05JUN2020 | 09JUN2020 | - 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 50 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-------------------------------|--|-----------------|---|
| 10068 50 µg Younger | Injection site reactions (pain, discomfort with movement) Injection site reaction | 05JUN2020 12:00 | 12JUN2020 9:01 | 165.0 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Abdominal cramps Abdominal pain | 05JUN2020 19:30 | 05JUN2020 21:00 | 1.5 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Pain in the legs Pain in extremity | 05JUN2020 21:00 | 06JUN2020 | - 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Earache (both ears) Ear pain | 05JUN2020 21:30 | 06JUN2020 11:00 | 13.5 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Dizziness Dizziness | 06JUN2020 14:00 | 07JUN2020 15:00 | 25.0 2 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Hot flushes Hot flush | 06JUN2020 15:00 | 07JUN2020 11:00 | 20.0 2 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 51 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|--|--|-------------------------------|--|-----------------|---|
| 10070 50 µg Younger | Injection site reactions (pain, sensitivity at touch, swelling, redness) Injection site reaction | 15MAY2020 20:00 | 19MAY2020 23:00 | 99.0 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Flu-like symptoms (loss of appetite, fatigue, malaise, chills) Influenza like illness | 16MAY2020 0:00 | 19MAY2020 6:30 | 78.5 2 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Flu-like symptoms (Headache, chills, malaise, fatigue) Influenza like illness | 05JUN2020 | 07JUN2020 | - 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Injection site reactions (pain, discomfort with movement) Injection site reaction | 05JUN2020 13:34 | 08JUN2020 | - 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10073 50 µg Younger | Flu-like symptoms (malaise, tiredness, chills) Influenza like illness | 15MAY2020 14:30 | 17MAY2020 17:00 | 50.5 1 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Sensitivity at touch of injection site Injection site hypersensitivity | 16MAY2020 8:00 | 17MAY2020 12:00 | 28.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 52 of 66) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10073 50 µg Younger | Lower abdominal pain (menses) Dysmenorrhoea | 27MAY2020 15:05 | 27MAY2020 22:00 | 6.9 13 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Tension headache Tension headache | 30MAY2020 7:30 | 30MAY2020 13:00 | 5.5 16 | Dose Not Changed Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Flu-like symptoms (Headache, chills, nausea, vomiting, loss of appetite, fatigue, malaise) Influenza like illness | 05JUN2020 13:00 | 11JUN2020 | - 1 | Not Applicable Yes | Related Recovered/Resolved | Severe No | Yes No | No Yes |
| | Injection site reactions (pain, significant discomfort at rest) Injection site reaction | 05JUN2020 13:00 | 10JUN2020 | - 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Sore throat Oropharyngeal pain | 05JUN2020 18:00 | 06JUN2020 22:00 | 28.0 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Circulatory problems Cardiovascular disorder | 05JUN2020 20:00 | 06JUN2020 23:00 | 27.0 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 53 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10073 50 µg Younger | Dizziness Dizziness | 05JUN2020 20:00 | 06JUN2020 23:00 | 27.0 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Tension headache Tension headache | 15JUN2020 10:00 | 15JUN2020 16:00 | 6.0 11 | Not Applicable Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 10066 60 µg Younger | Injection site reactions (discomfort with movement, pain) Injection site reaction | 19MAY2020 14:00 | 23MAY2020 6:00 | 88.0 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Headache Headache | 19MAY2020 18:00 | 21MAY2020 6:00 | 36.0 1 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | flu-like symptoms Influenza like illness | 19MAY2020 21:30 | 25MAY2020 7:00 | 129.5 1 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | pyrexia (highest values 39,2) Pyrexia | 19MAY2020 21:55 | 21MAY2020 21:55 | 48.0 1 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 54 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10066 60 µg Younger | Headache Headache | 12JUN2020 13:30 | 12JUN2020 15:30 | 2.0 25 | Not Applicable Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 10075 60 µg Younger | Flatulence Flatulence | 22MAY2020 | 24MAY2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Headache Headache | 22MAY2020 | 27MAY2020 8:00 | - 1 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Flu-like symptoms (tiredness, myalgia, arthralgia, loss of appetite, chills, malaise) Influenza like illness | 22MAY2020 | 26MAY2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Pyrexia Pyrexia | 22MAY2020 | 24MAY2020 8:00 | - 1 | Drug Withdrawn Yes | Related Recovered/Resolved | Severe No | Yes No | No Yes |
| | Injection site reactions (discomfort with movement, pain) Injection site reaction | 22MAY2020 14:30 | 28MAY2020 8:00 | 137.5 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 55 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10075 60 µg Younger | Ear pain (both sides) Ear pain | 22MAY2020 16:00 | 24MAY2020 8:00 | 40.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Tinea pedis right foot Tinea pedis | 08JUN2020 20:00 | 27JUN2020 18:00 | 454.0 18 | Not Applicable Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Toothache wisdomtooth Toothache | 24JUN2020 7:00 | 01JUL2020 10:00 | 171.0 34 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | No No | No No |
| 10076 60 µg Younger | Pain at injection site Injection site pain | 22MAY2020 15:20 | 24MAY2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Flu-like symptoms (tiredness, chills, myalgia) Influenza like illness | 22MAY2020 22:00 | 24MAY2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Mild discomfort to touch at injection site Injection site discomfort | 23MAY2020 8:30 | 24MAY2020 | - 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 56 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-------------------------------|--|-----------------|---|
| 10078 60 µg Younger | Flu-like symptoms (myalgia, chills, tiredness) Influenza like illness | 22MAY2020 18:00 | 24MAY2020 7:00 | 37.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Injection site reactions (pain, discomfort to touch, discomfort with movement) Injection site reaction | 22MAY2020 18:00 | 24MAY2020 7:00 | 37.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10083 60 µg Younger | Orthostatic dysregulation (vasovagal reaction) Presyncope | 20MAY2020 18:40 | 20MAY2020 18:50 | 0.2 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | flu-like symptoms Influenza like illness | 20MAY2020 18:45 | 22MAY2020 6:30 | 35.8 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | pain at injection site Injection site pain | 20MAY2020 19:00 | 23MAY2020 7:00 | 60.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10084 60 µg Younger | Flu-like symptoms (myalgia, nausea, chills, tirednes, malaise, loss of appetite, headache) Influenza like illness | 22MAY2020 | 24MAY2020 7:00 | - 1 | Dose Not Changed Yes | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 57 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|--|--|-------------------------------|--|-----------------|---|
| 10084 60 µg Younger | Mild numbness at injection site (2-3 cm) Injection site hypoaesthesia | 22MAY2020 19:00 | 23MAY2020 9:16 | 14.3 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | intermittent Pyrexia Pyrexia | 22MAY2020 22:00 | 26MAY2020 20:30 | 94.5 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Cough Cough | 23MAY2020 17:00 | 24MAY2020 10:00 | 17.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Pain at injection site (left arm) Injection site pain | 15JUN2020 7:00 | 19JUN2020 18:00 | 107.0 25 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10085 60 µg Younger | Flu-like symptoms Influenza like illness | 22MAY2020 | 25MAY2020 | - 1 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Injection site reactions (pain, discomfort with movement) Injection site reaction | 22MAY2020 16:00 | 25MAY2020 14:00 | 70.0 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 58 of 66) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10085 60 µg Younger | Increased sensitivity of the skin all over Hyperaesthesia | 22MAY2020 20:00 | 24MAY2020 11:00 | 39.0 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10089 60 µg Younger | flu like symptoms (headache, nausea) Influenza like illness | 20MAY2020 10:25 | 22MAY2020 7:00 | 44.6 1 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | intermittend vomiting (4x) Vomiting | 20MAY2020 12:06 | 20MAY2020 21:58 | 9.9 1 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Injection site reactions (pain, discomfort with movement, discomfort to touch) Injection site reaction | 20MAY2020 18:00 | 23MAY2020 15:00 | 69.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Headache Headache | 05JUL2020 2:01 | 05JUL2020 2:45 | 0.7 47 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | No No | No No |
| 10093 60 µg Younger | Injection site reactions (painm discomfort with movement) Injection site reaction | 20MAY2020 19:00 | 22MAY2020 7:00 | 36.0 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 59 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|--|--|-------------------------------|--|-----------------|---|
| 10093 60 µg Younger | head pressure Head discomfort | 20MAY2020 22:00 | 22MAY2020 7:00 | 33.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | flu-like symptoms (chills, malaise, tiredness, headache, nausea) Influenza like illness | 21MAY2020 9:00 | 24MAY2020 7:00 | 70.0 2 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Elevation of gamma-GT > 2,5 ULN Gamma-glutamyltransferase increased | 27MAY2020 8:28 | 08JUN2020 7:47 | 287.3 8 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10096 60 µg Younger | pain at injection site Injection site pain | 19MAY2020 12:08 | 21MAY2020 8:25 | 44.3 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Mild discomfort to touch at injection site Injection site discomfort | 19MAY2020 12:08 | 21MAY2020 8:25 | 44.3 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Headache Headache | 19MAY2020 20:00 | 19MAY2020 23:00 | 3.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 60 of 66) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-------------------------------|--|-----------------|---|
| 10096 60 µg Younger | flu-like symptoms (arthralgia, Myalgia, chills, malaise, elevated body temperature) Influenza like illness | 19MAY2020 22:00 | 21MAY2020 8:25 | 34.4 1 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | sleeping disorder Sleep disorder | 19MAY2020 23:00 | 20MAY2020 5:50 | 6.8 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Sore throat Oropharyngeal pain | 20MAY2020 5:50 | 21MAY2020 8:25 | 26.6 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10103 60 µg Younger | Injection site reactions (mild discomfort to touch, discomfort with movement) Injection site reaction | 22MAY2020 14:05 | 24MAY2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Flu-like symptoms (myalgia, chills, pyrexia) Influenza like illness | 22MAY2020 19:07 | 24MAY2020 | - 1 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10104 60 µg Younger | Injection site reactions (discomfort with movement, pain) Injection site reaction | 20MAY2020 16:00 | 24MAY2020 19:00 | 99.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 61 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 10104 60 µg Younger | flu-like symptoms (malaise, chills, tiredness, myalgia, elevated body temperature, headache) Influenza like illness | 20MAY2020 18:00 | 22MAY2020 8:00 | 38.0 1 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10282 10 µg Older | Dry cough Cough | 06SEP2020 7:00 | 13SEP2020 7:00 | 168.0 18 | Dose Not Changed No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10286 10 µg Older | Migraine Migraine | 04SEP2020 18:00 | 05SEP2020 7:00 | 13.0 11 | Dose Not Changed Yes | Not Related Recovered/Resolved | Severe No | Yes No | No No |
| 10291 10 µg Older | Dry cough Cough | 14SEP2020 20:00 | 15SEP2020 23:00 | 27.0 21 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20211 20 µg Older | skin burn left forearm Thermal burn | 27SEP2020 9:00 | 01OCT2020 | - 20 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20242 20 µg Older | pain left costal arch and shoulder Musculoskeletal pain | 18SEP2020 19:00 | | - 10 | Yes | Not Related | Moderate No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 62 of 66) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20242 20 µg Older | pain left costal arch and shoulder Musculoskeletal chest pain | 18SEP2020 19:00 | | - 10 | Yes | Not Related | Moderate No | Yes No | No No |
| | syncope Syncope | 20SEP2020 3:05 | 24SEP2020 | - 12 | Drug Withdrawn No | Not Related Recovered/Resolved | Severe Yes | Yes No | No No |
| 20243 20 µg Older | wasp sting (left cheek) Arthropod sting | 10SEP2020 15:00 | 14SEP2020 10:00 | 91.0 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | No No | No No |
| 10352 30 µg Older | Intermittent sore throat Oropharyngeal pain | 26SEP2020 10:00 | 28SEP2020 11:30 | 49.5 5 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10353 30 µg Older | Common cold Nasopharyngitis | 14OCT2020 9:00 | | - 2 | Not Applicable | Not Related | Mild No | Yes No | No No |
| 10358 30 µg Older | Dizziness intermittent Dizziness | 23SEP2020 9:00 | 28SEP2020 18:00 | 129.0 1 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 63 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 10358 30 µg Older | Symptoms common cold Nasopharyngitis | 06OCT2020 14:30 | 08OCT2020 16:45 | 50.3 14 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Heart burn Dyspepsia | 07OCT2020 7:00 | 13OCT2020 10:00 | 147.0 15 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 10361 30 µg Older | Pollakisuria Pollakiuria | 25SEP2020 22:00 | 26SEP2020 6:00 | 8.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Sleeping disorder Sleep disorder | 25SEP2020 22:00 | 26SEP2020 6:00 | 8.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Stomachpain Abdominal pain upper | 26SEP2020 0:00 | 26SEP2020 4:30 | 4.5 2 | Dose Not Changed No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Stomach pain Abdominal pain upper | 16OCT2020 20:15 | 16OCT2020 23:00 | 2.8 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 64 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10362 30 µg Older | pollakisuria intermittent Pollakiuria | 26SEP2020 0:00 | 27SEP2020 21:00 | 45.0 2 | Dose Not Changed No | Not Related Recovered/Resolved | Severe No | Yes No | No No |
| 10363 30 µg Older | Sleeping disorder Sleep disorder | 25SEP2020 22:00 | 26SEP2020 7:00 | 9.0 1 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Sore throat Oropharyngeal pain | 26SEP2020 20:30 | 27SEP2020 10:00 | 13.5 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Loss of hair Alopecia | 28SEP2020 | | - 4 | Dose Not Changed No | Related | Moderate No | Yes No | No No |
| 10364 30 µg Older | Pollakisuria Pollakiuria | 25SEP2020 22:00 | 26SEP2020 6:00 | 8.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Pollakisuria Bladder dysfunction | 16OCT2020 23:30 | 17OCT2020 7:00 | 7.5 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 65 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-1: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---------------------------------|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10365 30 µg Older | Pain ear right Ear pain | 03OCT2020 22:00 | 03OCT2020 23:30 | 1.5 11 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Pain ear right Ear pain | 04OCT2020 22:00 | 04OCT2020 23:00 | 1.0 12 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Vertigo intermittent Vertigo | 14OCT2020 21:00 | 19OCT2020 17:30 | 116.5 1 | Not Applicable No | Related Recovered/Resolved | Severe No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 66 of 66)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.6-1: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10018 1 µg Younger | Increased Lymphocytes Lymphocyte count increased | 27MAY2020 8:58 | 17JUN2020 8:13 | 503.3 8 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10025 1 µg Younger | Tired, irritated eyes Asthenopia | 28MAY2020 17:00 | 31MAY2020 22:00 | 77.0 3 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Tired, irritated eyes Eye irritation | 28MAY2020 17:00 | 31MAY2020 22:00 | 77.0 3 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10040 1 µg Younger | Flu like symptoms (headache, myalgia, arthralgia, nausea, tiredness) Influenza like illness | 29MAY2020 12:37 | 12JUN2020 | - 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Injection site reactions (pain, discomfort to touch, hardening, swelling) Injection site reaction | 30MAY2020 | 10JUN2020 20:00 | - 2 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Cervicobrachialgia Cervicobrachial syndrome | 12JUN2020 14:00 | 01AUG2020 6:00 | 1192.0 15 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 1 of 19)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.6-1: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 10040 1 µg Younger | Headache Headache | 12JUN2020 18:00 | 01AUG2020 6:00 | 1188.0 15 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10041 1 µg Younger | Itching at head and back Pruritus | 12MAY2020 21:20 | 12MAY2020 | - 5 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Pain right hand Pain in extremity | 14MAY2020 14:00 | 14MAY2020 21:00 | 7.0 7 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Paraesthesia left arm (injection site) due to myogelosis scapulae Injection site paraesthesia | 18MAY2020 7:50 | 08JUL2020 8:00 | 1224.2 11 | Dose Not Changed No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | reduction of power left arm due to myogelosis scapulae Myalgia | 18MAY2020 7:50 | 08JUL2020 8:00 | 1224.2 11 | Dose Not Changed No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Paraesthesia left arm (injection site) due to myogelosis scapulae Myosclerosis | 18MAY2020 7:50 | 08JUL2020 8:00 | 1224.2 11 | Dose Not Changed No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 2 of 19)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.6-1: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10041 1 µg Younger | reduction of power left arm due to myogelosis scapulae Muscle strength abnormal | 18MAY2020 7:50 | 08JUL2020 8:00 | 1224.2 11 | Dose Not Changed No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Loss of appetite Decreased appetite | 29MAY2020 21:00 | 06JUN2020 12:00 | 183.0 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Dry mouth Dry mouth | 31MAY2020 1:30 | 07JUN2020 7:00 | 173.5 3 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Taste disorders Taste disorder | 31MAY2020 1:30 | 06JUN2020 12:00 | 154.5 3 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Massive tension at neck Muscle tightness | 04JUN2020 | 08JUL2020 8:00 | - 7 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Headache Headache | 04JUN2020 4:00 | 11JUN2020 8:00 | 172.0 7 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 3 of 19)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.6-1: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10041 1 µg Younger | Pain injection arm Injection site pain | 04JUN2020 6:00 | 08JUL2020 8:00 | 818.0 7 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10042 1 µg Younger | Vasovagal immediate post-injection reaction Presyncope | 29MAY2020 10:01 | 29MAY2020 10:02 | 0.0 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10052 1 µg Younger | regular tachycardia (stress related) Tachycardia | 19JUN2020 9:00 | 25JUN2020 8:57 | 144.0 22 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 10003 10 µg Younger | Injection site reactions (discomfort with movement, tenderness) Injection site reaction | 19MAY2020 11:30 | 27MAY2020 7:00 | 187.5 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10004 10 µg Younger | Cough Cough | 25APR2020 10:00 | 26APR2020 14:00 | 28.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Sore throat Oropharyngeal pain | 25APR2020 10:00 | 26APR2020 14:00 | 28.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 4 of 19)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.6-1: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10006 10 µg Younger | Gingivitis Gingivitis | 12MAY2020 17:00 | 16MAY2020 19:00 | 98.0 15 | Dose Not Changed Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | intermittent chest pain due to muscular tension Musculoskeletal chest pain | 14MAY2020 | 16MAY2020 9:30 | - 17 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Presyncope Presyncope | 20MAY2020 10:00 | 20MAY2020 10:01 | 0.0 2 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10008 10 µg Younger | Rhinitis allergica Rhinitis allergic | 27MAY2020 11:00 | 07JUN2020 10:00 | 263.0 9 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Pollen allergy Seasonal allergy | 10JUN2020 10:00 | 14JUN2020 12:00 | 98.0 23 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10010 10 µg Younger | Tiredness Fatigue | 24APR2020 | 07MAY2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 5 of 19)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.6-1: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|-------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 10010 10 µg Younger | Flu-like symptoms Influenza like illness | 25APR2020 10:10 | 07MAY2020 | - 2 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Injection site reactions (pain, tenderness, discomfort with movement) Injection site reaction | 25APR2020 13:00 | 03MAY2020 7:00 | 186.0 2 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | stress dyspnea Dyspnoea exertional | 27APR2020 | 07MAY2020 | - 4 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Cough Cough | 06MAY2020 7:00 | 07MAY2020 | - 13 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Verruca -> operation in local anesthesia Papilloma excision | 08MAY2020 | 08MAY2020 | - 15 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 10011 10 µg Younger | Genital herpes Genital herpes | 26APR2020 | 07MAY2020 | - 3 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 6 of 19)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.6-1: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10019 10 µg Younger | Intermittent headache Headache | 21MAY2020 8:00 | 28MAY2020 0:00 | 160.0 3 | Not Applicable Yes | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10171 20 µg Younger | Conjunctivitis right eye Conjunctivitis | 06AUG2020 12:00 | 08AUG2020 12:00 | 48.0 1 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Nasal congestion Nasal congestion | 06AUG2020 12:00 | 08AUG2020 12:00 | 48.0 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Swollen lymph node left axilla Lymphadenopathy | 09AUG2020 12:00 | 11AUG2020 12:00 | 48.0 4 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10172 20 µg Younger | Paresthesia of both arms Paraesthesia | 18JUL2020 6:30 | 18JUL2020 9:30 | 3.0 3 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10173 20 µg Younger | Throat pain with coarse voice Dysphonia | 18JUL2020 9:30 | 20JUL2020 8:10 | 46.7 3 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 7 of 19)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.6-1: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10173 20 µg Younger | Throat pain with coarse voice Oropharyngeal pain | 18JUL2020 9:30 | 20JUL2020 8:10 | 46.7 3 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10179 20 µg Younger | Depression Depression | 13AUG2020 7:00 | | - 8 | Not Applicable Yes | Not Related | Severe No | Yes No | No No |
| | Sleeping disorder Sleep disorder | 13AUG2020 20:00 | 02SEP2020 20:00 | 480.0 8 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10197 20 µg Younger | Gingival pain diffuse Gingival pain | 17JUL2020 20:30 | 19JUL2020 11:00 | 38.5 2 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Hallucinations Hallucination | 06AUG2020 20:30 | 08AUG2020 20:00 | 47.5 1 | Not Applicable No | Related Recovered/Resolved | Severe No | Yes No | No No |
| | Hypersensitivity to light (eyes) Photophobia | 07AUG2020 7:30 | 09AUG2020 10:00 | 50.5 2 | Not Applicable No | Related Recovered/Resolved | Severe No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 8 of 19)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.6-1: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10197 20 µg Younger | thoracic pain (musculoskeletal) Musculoskeletal chest pain | 07AUG2020 7:30 | 12AUG2020 23:00 | 135.5 2 | Not Applicable No | Related Recovered/Resolved | Severe No | Yes No | No No |
| 10020 30 µg Younger | Pain in lumbar region Back pain | 20MAY2020 | 22MAY2020 7:00 | - 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Lumbalgia Back pain | 13JUN2020 10:00 | 17JUN2020 14:00 | 100.0 25 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10028 30 µg Younger | Hyperpigmentation of the skin at injection site Injection site discolouration | 14MAY2020 8:12 | 21MAY2020 7:00 | 166.8 8 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10031 30 µg Younger | Rhinitis Rhinitis | 09JUN2020 7:00 | 11JUN2020 7:00 | 48.0 13 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 10034 30 µg Younger | Haematoma at injection site Injection site haematoma | 12MAY2020 7:00 | 24MAY2020 7:00 | 288.0 8 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 9 of 19)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.6-1: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10043 30 µg Younger | Headache (due to muscle tension of the neck) Headache | 15MAY2020 | 01JUN2020 16:00 | - 9 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Headache (due to muscle tension of the neck) Muscle tightness | 15MAY2020 | 01JUN2020 16:00 | - 9 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 10047 30 µg Younger | Pityriasis rosea Pityriasis rosea | 08JUN2020 18:00 | 17JUL2020 0:00 | 918.0 12 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10049 50 µg Younger | Herpes simplex infection, lips and left nose nostril Oral herpes | 04JUN2020 17:00 | 13JUN2020 15:00 | 214.0 3 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Herpes simplex infection, lips and left nose nostril Nasal herpes | 04JUN2020 17:00 | 13JUN2020 15:00 | 214.0 3 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10050 50 µg Younger | menstrual pain Dysmenorrhoea | 23MAY2020 17:00 | 23MAY2020 18:00 | 1.0 9 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 10 of 19)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.6-1: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 10053 50 µg Younger | Hypotension during blood draw for CMI Blood pressure decreased | 12MAY2020 8:15 | 12MAY2020 8:29 | 0.2 1 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | No No | No No |
| 10055 50 µg Younger | Haematoma at injection side Injection site haematoma | 04JUN2020 11:00 | 13JUN2020 16:00 | 221.0 2 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10056 50 µg Younger | Cough Cough | 15MAY2020 0:00 | 19MAY2020 0:00 | 96.0 3 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10057 50 µg Younger | Tinea pedis of right foot Tinea pedis | 06JUN2020 | 02JUL2020 20:00 | - 2 | Not Applicable Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Inguinal mycosis Fungal infection | 13JUN2020 19:00 | 19JUN2020 20:00 | 145.0 9 | Not Applicable Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Dysphagia Dysphagia | 14JUN2020 19:00 | 17JUN2020 19:00 | 72.0 10 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> | | | | | | | | | |
| <p>Program: Lsaf_AE_2.sas (Page 11 of 19)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.6-1: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10059 50 µg Younger | Injection site reactions (pain, tenderness) Injection site reaction | 03JUN2020 11:50 | 11JUN2020 8:00 | 188.2 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10068 50 µg Younger | Injection site reactions (pain, discomfort with movement) Injection site reaction | 05JUN2020 12:00 | 12JUN2020 9:01 | 165.0 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Pain in the legs Pain in extremity | 05JUN2020 21:00 | 06JUN2020 | - 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Earache (both ears) Ear pain | 05JUN2020 21:30 | 06JUN2020 11:00 | 13.5 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10073 50 µg Younger | Lower abdominal pain (menses) Dysmenorrhoea | 27MAY2020 15:05 | 27MAY2020 22:00 | 6.9 13 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Tension headache Tension headache | 30MAY2020 7:30 | 30MAY2020 13:00 | 5.5 16 | Dose Not Changed Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. | | | | | | | | | |
| Program: Lsaf_AE_2.sas (Page 12 of 19) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.6-1: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10073 50 µg Younger | Sore throat Oropharyngeal pain | 05JUN2020 18:00 | 06JUN2020 22:00 | 28.0 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Circulatory problems Cardiovascular disorder | 05JUN2020 20:00 | 06JUN2020 23:00 | 27.0 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Tension headache Tension headache | 15JUN2020 10:00 | 15JUN2020 16:00 | 6.0 11 | Not Applicable Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 10075 60 µg Younger | Flatulence Flatulence | 22MAY2020 | 24MAY2020 | - 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Ear pain (both sides) Ear pain | 22MAY2020 16:00 | 24MAY2020 8:00 | 40.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Tinea pedis right foot Tinea pedis | 08JUN2020 20:00 | 27JUN2020 18:00 | 454.0 18 | Not Applicable Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 13 of 19)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.6-1: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10075 60 µg Younger | Toothache wisdomtooth Toothache | 24JUN2020 7:00 | 01JUL2020 10:00 | 171.0 34 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | No No | No No |
| 10083 60 µg Younger | Orthostatic dysregulation (vasovagal reaction) Presyncope | 20MAY2020 18:40 | 20MAY2020 18:50 | 0.2 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10084 60 µg Younger | Cough Cough | 23MAY2020 17:00 | 24MAY2020 10:00 | 17.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10085 60 µg Younger | Increased sensitivity of the skin all over Hyperaesthesia | 22MAY2020 20:00 | 24MAY2020 11:00 | 39.0 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10093 60 µg Younger | Elevation of gamma-GT > 2,5 ULN Gamma-glutamyltransferase increased | 27MAY2020 8:28 | 08JUN2020 7:47 | 287.3 8 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10096 60 µg Younger | sleeping disorder Sleep disorder | 19MAY2020 23:00 | 20MAY2020 5:50 | 6.8 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 14 of 19)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.6-1: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 10096 60 µg Younger | Sore throat Oropharyngeal pain | 20MAY2020 5:50 | 21MAY2020 8:25 | 26.6 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10282 10 µg Older | Dry cough Cough | 06SEP2020 7:00 | 13SEP2020 7:00 | 168.0 18 | Dose Not Changed No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10286 10 µg Older | Migraine Migraine | 04SEP2020 18:00 | 05SEP2020 7:00 | 13.0 11 | Dose Not Changed Yes | Not Related Recovered/Resolved | Severe No | Yes No | No No |
| 10291 10 µg Older | Dry cough Cough | 14SEP2020 20:00 | 15SEP2020 23:00 | 27.0 21 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20211 20 µg Older | skin burn left forearm Thermal burn | 27SEP2020 9:00 | 01OCT2020 | - 20 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20242 20 µg Older | pain left costal arch and shoulder Musculoskeletal pain | 18SEP2020 19:00 | | - 10 | Yes | Not Related | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 15 of 19)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.6-1: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20242 20 µg Older | pain left costal arch and shoulder Musculoskeletal chest pain | 18SEP2020 19:00 | | - 10 | Yes | Not Related | Moderate No | Yes No | No No |
| | syncope Syncope | 20SEP2020 3:05 | 24SEP2020 | - 12 | Drug Withdrawn No | Not Related Recovered/Resolved | Severe Yes | Yes No | No No |
| 20243 20 µg Older | wasp sting (left cheek) Arthropod sting | 10SEP2020 15:00 | 14SEP2020 10:00 | 91.0 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | No No | No No |
| 10352 30 µg Older | Intermittent sore throat Oropharyngeal pain | 26SEP2020 10:00 | 28SEP2020 11:30 | 49.5 5 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10353 30 µg Older | Common cold Nasopharyngitis | 14OCT2020 9:00 | | - 2 | Not Applicable | Not Related | Mild No | Yes No | No No |
| 10358 30 µg Older | Symptoms common cold Nasopharyngitis | 06OCT2020 14:30 | 08OCT2020 16:45 | 50.3 14 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 16 of 19)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.6-1: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10358 30 µg Older | Heart burn Dyspepsia | 07OCT2020 7:00 | 13OCT2020 10:00 | 147.0 15 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 10361 30 µg Older | Pollakisuria Pollakiuria | 25SEP2020 22:00 | 26SEP2020 6:00 | 8.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Sleeping disorder Sleep disorder | 25SEP2020 22:00 | 26SEP2020 6:00 | 8.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Stomachpain Abdominal pain upper | 26SEP2020 0:00 | 26SEP2020 4:30 | 4.5 2 | Dose Not Changed No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Stomach pain Abdominal pain upper | 16OCT2020 20:15 | 16OCT2020 23:00 | 2.8 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10362 30 µg Older | pollakisuria intermittent Pollakiuria | 26SEP2020 0:00 | 27SEP2020 21:00 | 45.0 2 | Dose Not Changed No | Not Related Recovered/Resolved | Severe No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 17 of 19)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.6-1: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|-------------------------------------|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 10363 30 µg Older | Sleeping disorder Sleep disorder | 25SEP2020 22:00 | 26SEP2020 7:00 | 9.0 1 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Sore throat Oropharyngeal pain | 26SEP2020 20:30 | 27SEP2020 10:00 | 13.5 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Loss of hair Alopecia | 28SEP2020 | | - 4 | Dose Not Changed No | Related | Moderate No | Yes No | No No |
| 10364 30 µg Older | Pollakisuria Pollakiuria | 25SEP2020 22:00 | 26SEP2020 6:00 | 8.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Pollakisuria Bladder dysfunction | 16OCT2020 23:30 | 17OCT2020 7:00 | 7.5 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 10365 30 µg Older | Pain ear right Ear pain | 03OCT2020 22:00 | 03OCT2020 23:30 | 1.5 11 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 18 of 19)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.6-1: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---------------------------------|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10365 30 µg Older | Pain ear right Ear pain | 04OCT2020 22:00 | 04OCT2020 23:00 | 1.0 12 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Vertigo intermittent Vertigo | 14OCT2020 21:00 | 19OCT2020 17:30 | 116.5 1 | Not Applicable No | Related Recovered/Resolved | Severe No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 19 of 19)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 1 µg Younger | 20153 | 29JUN2020 21:30 | Tenderness | Mild | 0 | | 29JUN2020 8:10 |
| | | 20JUL2020 21:30 | Tenderness | Mild | 21 | 0 | 29JUN2020 8:10 |
| | 20158 | 13JUL2020 19:30 | Tenderness | Moderate | 0 | | 13JUL2020 8:00 |
| | | 14JUL2020 19:30 | Tenderness | Moderate | 1 | | 13JUL2020 8:00 |
| | | 03AUG2020 19:30 | Tenderness | Mild | 21 | 0 | 13JUL2020 8:00 |
| | | 04AUG2020 19:20 | Tenderness | Mild | 22 | 1 | 13JUL2020 8:00 |
| | 20160 | 29JUN2020 21:51 | Pain | Mild | 0 | | 29JUN2020 8:40 |
| | 20164 | 13JUL2020 19:00 | Pain | Mild | 0 | | 13JUL2020 9:30 |
| | | 13JUL2020 19:00 | Tenderness | Moderate | 0 | | 13JUL2020 9:30 |
| | | 14JUL2020 23:00 | Pain | Mild | 1 | | 13JUL2020 9:30 |
| | | 14JUL2020 23:00 | Tenderness | Moderate | 1 | | 13JUL2020 9:30 |
| | | 15JUL2020 22:55 | Tenderness | Mild | 2 | | 13JUL2020 9:30 |
| | | 17JUL2020 23:55 | Tenderness | Mild | 4 | | 13JUL2020 9:30 |
| | | 03AUG2020 19:50 | Pain | Mild | 21 | 0 | 13JUL2020 9:30 |
| | | 03AUG2020 19:50 | Tenderness | Mild | 21 | 0 | 13JUL2020 9:30 |
| | | 04AUG2020 21:20 | Pain | Mild | 22 | 1 | 13JUL2020 9:30 |
| | | 04AUG2020 21:20 | Tenderness | Mild | 22 | 1 | 13JUL2020 9:30 |
| 05AUG2020 23:00 | Pain | Mild | 23 | 2 | 13JUL2020 9:30 | | |
| Program: Lsaf_locR_1.sas (Page 1 of 30) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

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Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--------------|----------------|-------------------------|-----------------|---------------------|---|---|---------------------------------|
| 1 µg Younger | 20164 | 05AUG2020 23:00 | Tenderness | Mild | 23 | 2 | 13JUL2020 9:30 |
| | | 06AUG2020 22:00 | Tenderness | Mild | 24 | 3 | 13JUL2020 9:30 |
| | 20171 | 03AUG2020 22:10 | Pain | Mild | 21 | 0 | 13JUL2020 8:30 |
| | | 03AUG2020 22:10 | Tenderness | Mild | 21 | 0 | 13JUL2020 8:30 |
| | | 04AUG2020 21:15 | Pain | Mild | 22 | 1 | 13JUL2020 8:30 |
| | | 04AUG2020 21:15 | Tenderness | Mild | 22 | 1 | 13JUL2020 8:30 |
| | 20181 | 28JUL2020 20:10 | Pain | Mild | 0 | | 28JUL2020 9:00 |
| | | 28JUL2020 20:10 | Tenderness | Mild | 0 | | 28JUL2020 9:00 |
| | 20188 | 28JUL2020 21:00 | Pain | Mild | 0 | | 28JUL2020 8:00 |
| | 3 µg Younger | 20185 | 29JUL2020 21:05 | Tenderness | Mild | 0 | |
| 20191 | | 06AUG2020 18:00 | Pain | Mild | 0 | | 06AUG2020 8:06 |
| | | 06AUG2020 18:00 | Tenderness | Mild | 0 | | 06AUG2020 8:06 |
| | | 07AUG2020 18:00 | Pain | Mild | 1 | | 06AUG2020 8:06 |
| | | 07AUG2020 18:00 | Tenderness | Mild | 1 | | 06AUG2020 8:06 |
| | | 26AUG2020 18:00 | Pain | Mild | 20 | 0 | 06AUG2020 8:06 |
| | | 26AUG2020 18:00 | Tenderness | Mild | 20 | 0 | 06AUG2020 8:06 |
| | | 27AUG2020 18:00 | Pain | Mild | 21 | 1 | 06AUG2020 8:06 |
| | | 27AUG2020 18:00 | Tenderness | Mild | 21 | 1 | 06AUG2020 8:06 |

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Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

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Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---|-----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 3 µg Younger | 20192 | 28JUL2020 18:00 | Tenderness | Mild | 0 | | 28JUL2020 10:00 |
| | | 29JUL2020 18:00 | Tenderness | Mild | 1 | | 28JUL2020 10:00 |
| | | 18AUG2020 20:00 | Tenderness | Mild | 21 | 0 | 28JUL2020 10:00 |
| | 20193 | 29JUL2020 22:50 | Pain | Mild | 0 | | 29JUL2020 8:30 |
| | | 29JUL2020 22:50 | Tenderness | Mild | 0 | | 29JUL2020 8:30 |
| | 20194 | 30JUL2020 22:00 | Tenderness | Mild | 1 | | 29JUL2020 9:30 |
| | | 18AUG2020 21:00 | Tenderness | Mild | 20 | 0 | 29JUL2020 9:30 |
| | 20195 | 01AUG2020 19:20 | Pain | Mild | 1 | | 31JUL2020 9:07 |
| | | 01AUG2020 19:20 | Tenderness | Mild | 1 | | 31JUL2020 9:07 |
| | | 20AUG2020 20:10 | Pain | Mild | 20 | 1 | 31JUL2020 9:07 |
| | | 21AUG2020 20:10 | Pain | Mild | 21 | 2 | 31JUL2020 9:07 |
| | 20197 | 18AUG2020 20:23 | Tenderness | Mild | 21 | 0 | 28JUL2020 9:30 |
| | 20201 | 06AUG2020 21:00 | Tenderness | Moderate | 0 | | 06AUG2020 8:36 |
| | | 26AUG2020 21:00 | Pain | Mild | 20 | 0 | 06AUG2020 8:36 |
| | | 26AUG2020 21:00 | Tenderness | Mild | 20 | 0 | 06AUG2020 8:36 |
| | | 27AUG2020 21:00 | Pain | Mild | 21 | 1 | 06AUG2020 8:36 |
| | | 27AUG2020 21:00 | Tenderness | Mild | 21 | 1 | 06AUG2020 8:36 |
| 20203 | 31JUL2020 19:28 | Pain | Mild | 0 | | 31JUL2020 9:37 | |
| Program: Lsaf_locR_1.sas (Page 3 of 30) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 3 µg Younger | 20203 | 31JUL2020 19:28 | Tenderness | Mild | 0 | | 31JUL2020 9:37 |
| | | 01AUG2020 21:54 | Pain | Mild | 1 | | 31JUL2020 9:37 |
| | | 01AUG2020 21:54 | Tenderness | Moderate | 1 | | 31JUL2020 9:37 |
| | | 02AUG2020 21:48 | Tenderness | Mild | 2 | | 31JUL2020 9:37 |
| | | 21AUG2020 21:45 | Pain | Mild | 21 | 0 | 31JUL2020 9:37 |
| | | 21AUG2020 21:45 | Tenderness | Mild | 21 | 0 | 31JUL2020 9:37 |
| | | 22AUG2020 22:03 | Pain | Mild | 22 | 1 | 31JUL2020 9:37 |
| | | 22AUG2020 22:03 | Tenderness | Mild | 22 | 1 | 31JUL2020 9:37 |
| | | 23AUG2020 22:28 | Tenderness | Mild | 23 | 2 | 31JUL2020 9:37 |
| | 20204 | 31JUL2020 21:14 | Pain | Mild | 0 | | 31JUL2020 10:07 |
| | | 31JUL2020 21:14 | Tenderness | Mild | 0 | | 31JUL2020 10:07 |
| | | 19AUG2020 21:23 | Pain | Mild | 19 | 0 | 31JUL2020 10:07 |
| | | 19AUG2020 21:23 | Tenderness | Mild | 19 | 0 | 31JUL2020 10:07 |
| 10 µg Younger | 20101 | 16JUN2020 22:00 | Pain | Mild | 0 | | 16JUN2020 8:45 |
| | | 17JUN2020 22:00 | Pain | Mild | 1 | | 16JUN2020 8:45 |
| | | 07JUL2020 22:00 | Pain | Mild | 21 | 0 | 16JUN2020 8:45 |
| | | 07JUL2020 22:00 | Tenderness | Mild | 21 | 0 | 16JUN2020 8:45 |
| | | 08JUL2020 22:00 | Pain | Mild | 22 | 1 | 16JUN2020 8:45 |
| Program: Lsaf_locR_1.sas (Page 4 of 30) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|---------------|---|-------------------------|----------------|---------------------|---|---|---------------------------------|--|
| 10 µg Younger | 20101 | 08JUL2020 22:00 | Tenderness | Mild | 22 | 1 | 16JUN2020 8:45 | |
| | 20102 | 16JUN2020 20:00 | Pain | Mild | 0 | | 16JUN2020 7:45 | |
| | | 16JUN2020 20:00 | Tenderness | Moderate | 0 | | 16JUN2020 7:45 | |
| | | 07JUL2020 20:00 | Pain | Mild | 21 | 0 | 16JUN2020 7:45 | |
| | | 08JUL2020 20:00 | Pain | Mild | 22 | 1 | 16JUN2020 7:45 | |
| | 20103 | 16JUN2020 20:29 | Pain | Mild | 1 | | 15JUN2020 9:22 | |
| | | 16JUN2020 20:29 | Tenderness | Mild | 1 | | 15JUN2020 9:22 | |
| | | 06JUL2020 21:00 | Pain | Mild | 21 | 0 | 15JUN2020 9:22 | |
| | | 06JUL2020 21:00 | Tenderness | Mild | 21 | 0 | 15JUN2020 9:22 | |
| | | 07JUL2020 20:55 | Pain | Mild | 22 | 1 | 15JUN2020 9:22 | |
| | | 07JUL2020 20:55 | Tenderness | Mild | 22 | 1 | 15JUN2020 9:22 | |
| | | 08JUL2020 20:55 | Pain | Mild | 23 | 2 | 15JUN2020 9:22 | |
| | | 08JUL2020 20:55 | Tenderness | Mild | 23 | 2 | 15JUN2020 9:22 | |
| | 20104 | 16JUN2020 19:45 | Pain | Mild | 0 | | 16JUN2020 9:45 | |
| | | 16JUN2020 19:45 | Tenderness | Mild | 0 | | 16JUN2020 9:45 | |
| | | 17JUN2020 19:45 | Pain | Mild | 1 | | 16JUN2020 9:45 | |
| | | 17JUN2020 19:45 | Tenderness | Mild | 1 | | 16JUN2020 9:45 | |
| | | 18JUN2020 20:00 | Pain | Mild | 2 | | 16JUN2020 9:45 | |
| | Program: Lsaf_locR_1.sas (Page 5 of 30) | | | | | | | |

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Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 10 µg Younger | 20104 | 18JUN2020 20:00 | Tenderness | Mild | 2 | | 16JUN2020 9:45 |
| | | 07JUL2020 21:00 | Tenderness | Mild | 21 | 0 | 16JUN2020 9:45 |
| | | 08JUL2020 20:45 | Pain | Mild | 22 | 1 | 16JUN2020 9:45 |
| | | 08JUL2020 20:45 | Tenderness | Mild | 22 | 1 | 16JUN2020 9:45 |
| | | 09JUL2020 20:50 | Tenderness | Mild | 23 | 2 | 16JUN2020 9:45 |
| | 20105 | 16JUN2020 21:12 | Pain | Mild | 0 | | 16JUN2020 10:47 |
| | | 16JUN2020 21:12 | Tenderness | Mild | 0 | | 16JUN2020 10:47 |
| | | 06JUL2020 20:02 | Pain | Mild | 20 | 0 | 16JUN2020 10:47 |
| | | 06JUL2020 20:02 | Tenderness | Mild | 20 | 0 | 16JUN2020 10:47 |
| | | 07JUL2020 20:00 | Pain | Mild | 21 | 1 | 16JUN2020 10:47 |
| | | 07JUL2020 20:00 | Tenderness | Mild | 21 | 1 | 16JUN2020 10:47 |
| | | 08JUL2020 20:05 | Tenderness | Mild | 22 | 2 | 16JUN2020 10:47 |
| | 20110 | 16JUN2020 20:15 | Pain | Mild | 0 | | 16JUN2020 11:48 |
| | | 16JUN2020 20:15 | Tenderness | Mild | 0 | | 16JUN2020 11:48 |
| | | 17JUN2020 20:30 | Pain | Mild | 1 | | 16JUN2020 11:48 |
| | | 17JUN2020 20:30 | Tenderness | Mild | 1 | | 16JUN2020 11:48 |
| | | 07JUL2020 20:30 | Pain | Mild | 21 | 0 | 16JUN2020 11:48 |
| | | 07JUL2020 20:30 | Tenderness | Mild | 21 | 0 | 16JUN2020 11:48 |
| Program: Lsaf_locR_1.sas (Page 6 of 30) | | | | | | | |

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Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|---|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 10 µg Younger | 20110 | 08JUL2020 20:00 | Pain | Mild | 22 | 1 | 16JUN2020 11:48 |
| | | 08JUL2020 20:00 | Tenderness | Moderate | 22 | 1 | 16JUN2020 11:48 |
| | 20111 | 18JUN2020 21:30 | Tenderness | Moderate | 0 | | 18JUN2020 11:00 |
| | | 19JUN2020 22:00 | Pain | Mild | 1 | | 18JUN2020 11:00 |
| | | 19JUN2020 22:00 | Tenderness | Moderate | 1 | | 18JUN2020 11:00 |
| | | 20JUN2020 21:30 | Tenderness | Mild | 2 | | 18JUN2020 11:00 |
| | 20114 | 18JUN2020 22:00 | Pain | Mild | 0 | | 18JUN2020 10:00 |
| | | 18JUN2020 22:00 | Tenderness | Moderate | 0 | | 18JUN2020 10:00 |
| | | 19JUN2020 22:00 | Pain | Mild | 1 | | 18JUN2020 10:00 |
| | | 19JUN2020 22:00 | Tenderness | Moderate | 1 | | 18JUN2020 10:00 |
| | | 20JUN2020 22:00 | Pain | Mild | 2 | | 18JUN2020 10:00 |
| | | 20JUN2020 22:00 | Tenderness | Mild | 2 | | 18JUN2020 10:00 |
| | | 09JUL2020 22:00 | Pain | Mild | 21 | 0 | 18JUN2020 10:00 |
| | | 09JUL2020 22:00 | Tenderness | Moderate | 21 | 0 | 18JUN2020 10:00 |
| | | 10JUL2020 22:00 | Pain | Mild | 22 | 1 | 18JUN2020 10:00 |
| | | 10JUL2020 22:00 | Tenderness | Moderate | 22 | 1 | 18JUN2020 10:00 |
| | | 10JUL2020 22:00 | Induration/Swelling | Mild | 22 | 1 | 18JUN2020 10:00 |
| | | 11JUL2020 22:00 | Pain | Mild | 23 | 2 | 18JUN2020 10:00 |
| | Program: Lsaf_locR_1.sas (Page 7 of 30) | | | | | | |

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Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|---------------|---|-------------------------|----------------|---------------------|---|---|---------------------------------|--|
| 10 µg Younger | 20114 | 11JUL2020 22:00 | Tenderness | Mild | 23 | 2 | 18JUN2020 10:00 | |
| | 20116 | 18JUN2020 22:04 | Pain | Moderate | 0 | | 18JUN2020 12:00 | |
| | | 18JUN2020 22:04 | Tenderness | Moderate | 0 | | 18JUN2020 12:00 | |
| | | 19JUN2020 22:52 | Pain | Mild | 1 | | 18JUN2020 12:00 | |
| | | 19JUN2020 22:52 | Tenderness | Moderate | 1 | | 18JUN2020 12:00 | |
| | 20117 | 18JUN2020 19:00 | Pain | Mild | 0 | | 18JUN2020 10:30 | |
| | | 18JUN2020 19:00 | Tenderness | Mild | 0 | | 18JUN2020 10:30 | |
| | | 19JUN2020 19:00 | Tenderness | Mild | 1 | | 18JUN2020 10:30 | |
| | | 20JUN2020 19:00 | Tenderness | Mild | 2 | | 18JUN2020 10:30 | |
| | | 09JUL2020 20:00 | Pain | Mild | 21 | 0 | 18JUN2020 10:30 | |
| | | 09JUL2020 20:00 | Tenderness | Mild | 21 | 0 | 18JUN2020 10:30 | |
| | 20118 | 18JUN2020 22:25 | Pain | Mild | 0 | | 18JUN2020 12:30 | |
| | | 18JUN2020 22:25 | Tenderness | Mild | 0 | | 18JUN2020 12:30 | |
| | | 19JUN2020 23:25 | Pain | Mild | 1 | | 18JUN2020 12:30 | |
| | | 19JUN2020 23:25 | Tenderness | Moderate | 1 | | 18JUN2020 12:30 | |
| | | 09JUL2020 20:55 | Pain | Mild | 21 | 0 | 18JUN2020 12:30 | |
| | | 09JUL2020 20:55 | Tenderness | Mild | 21 | 0 | 18JUN2020 12:30 | |
| | | 10JUL2020 21:00 | Pain | Mild | 22 | 1 | 18JUN2020 12:30 | |
| | Program: Lsaf_locR_1.sas (Page 8 of 30) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 10 µg Younger | 20118 | 10JUL2020 21:00 | Tenderness | Moderate | 22 | 1 | 18JUN2020 12:30 |
| | | 11JUL2020 19:35 | Pain | Mild | 23 | 2 | 18JUN2020 12:30 |
| | | 11JUL2020 19:35 | Tenderness | Mild | 23 | 2 | 18JUN2020 12:30 |
| | 20121 | 18JUN2020 22:00 | Tenderness | Moderate | 0 | | 18JUN2020 11:30 |
| | | 19JUN2020 22:00 | Pain | Mild | 1 | | 18JUN2020 11:30 |
| | | 19JUN2020 22:00 | Tenderness | Moderate | 1 | | 18JUN2020 11:30 |
| | | 20JUN2020 22:00 | Pain | Mild | 2 | | 18JUN2020 11:30 |
| | | 09JUL2020 22:00 | Pain | Mild | 21 | 0 | 18JUN2020 11:30 |
| | | 09JUL2020 22:00 | Tenderness | Moderate | 21 | 0 | 18JUN2020 11:30 |
| | | 10JUL2020 22:00 | Pain | Mild | 22 | 1 | 18JUN2020 11:30 |
| 20 µg Younger | 20156 | 02JUL2020 23:00 | Pain | Mild | 0 | | 02JUL2020 10:00 |
| | | 02JUL2020 23:00 | Tenderness | Mild | 0 | | 02JUL2020 10:00 |
| | | 03JUL2020 21:00 | Pain | Mild | 1 | | 02JUL2020 10:00 |
| | | 03JUL2020 21:00 | Tenderness | Mild | 1 | | 02JUL2020 10:00 |
| | | 23JUL2020 23:00 | Pain | Moderate | 21 | 0 | 02JUL2020 10:00 |
| | | 23JUL2020 23:00 | Tenderness | Mild | 21 | 0 | 02JUL2020 10:00 |
| | | 24JUL2020 23:00 | Pain | Mild | 22 | 1 | 02JUL2020 10:00 |
| | | 24JUL2020 23:00 | Tenderness | Mild | 22 | 1 | 02JUL2020 10:00 |
| Program: Lsaf_locR_1.sas (Page 9 of 30) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|--|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 20156 | 25JUL2020 23:00 | Pain | Mild | 23 | 2 | 02JUL2020 10:00 |
| | | 25JUL2020 23:00 | Tenderness | Mild | 23 | 2 | 02JUL2020 10:00 |
| | | 26JUL2020 23:00 | Pain | Mild | 24 | 3 | 02JUL2020 10:00 |
| | | 26JUL2020 23:00 | Tenderness | Mild | 24 | 3 | 02JUL2020 10:00 |
| | | 27JUL2020 23:00 | Tenderness | Mild | 25 | 4 | 02JUL2020 10:00 |
| | | 28JUL2020 23:00 | Tenderness | Mild | 26 | 5 | 02JUL2020 10:00 |
| | | 29JUL2020 23:00 | Tenderness | Mild | 27 | 6 | 02JUL2020 10:00 |
| | | 30JUL2020 9:04 | Tenderness | Mild | 28 | 7 | 02JUL2020 10:00 |
| | 20159 | 01JUL2020 20:13 | Pain | Mild | 0 | | 01JUL2020 8:00 |
| | | 01JUL2020 20:13 | Tenderness | Moderate | 0 | | 01JUL2020 8:00 |
| | | 02JUL2020 20:10 | Pain | Mild | 1 | | 01JUL2020 8:00 |
| | | 02JUL2020 20:10 | Tenderness | Mild | 1 | | 01JUL2020 8:00 |
| | | 03JUL2020 20:16 | Tenderness | Mild | 2 | | 01JUL2020 8:00 |
| | | 22JUL2020 20:00 | Pain | Mild | 21 | 0 | 01JUL2020 8:00 |
| | | 22JUL2020 20:00 | Tenderness | Mild | 21 | 0 | 01JUL2020 8:00 |
| | | 23JUL2020 20:06 | Pain | Mild | 22 | 1 | 01JUL2020 8:00 |
| | 23JUL2020 20:06 | Tenderness | Mild | 22 | 1 | 01JUL2020 8:00 | |
| | 20168 | 01JUL2020 21:00 | Pain | Moderate | 0 | | 01JUL2020 9:00 |
| | Program: Lsaf_locR_1.sas (Page 10 of 30) | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 20168 | 01JUL2020 21:00 | Tenderness | Moderate | 0 | | 01JUL2020 9:00 |
| | | 02JUL2020 22:00 | Pain | Moderate | 1 | | 01JUL2020 9:00 |
| | | 02JUL2020 22:00 | Tenderness | Moderate | 1 | | 01JUL2020 9:00 |
| | | 22JUL2020 22:00 | Pain | Mild | 21 | 0 | 01JUL2020 9:00 |
| | | 22JUL2020 22:00 | Tenderness | Mild | 21 | 0 | 01JUL2020 9:00 |
| | | 23JUL2020 23:00 | Pain | Mild | 22 | 1 | 01JUL2020 9:00 |
| | | 23JUL2020 23:00 | Tenderness | Mild | 22 | 1 | 01JUL2020 9:00 |
| | | 24JUL2020 21:30 | Pain | Mild | 23 | 2 | 01JUL2020 9:00 |
| | | 24JUL2020 21:30 | Tenderness | Mild | 23 | 2 | 01JUL2020 9:00 |
| | 20172 | 02JUL2020 19:40 | Pain | Moderate | 0 | | 02JUL2020 9:15 |
| | | 02JUL2020 19:40 | Tenderness | Moderate | 0 | | 02JUL2020 9:15 |
| | | 03JUL2020 19:50 | Pain | Moderate | 1 | | 02JUL2020 9:15 |
| | | 03JUL2020 19:50 | Tenderness | Moderate | 1 | | 02JUL2020 9:15 |
| | | 04JUL2020 19:45 | Pain | Mild | 2 | | 02JUL2020 9:15 |
| | | 04JUL2020 19:45 | Tenderness | Mild | 2 | | 02JUL2020 9:15 |
| | | 23JUL2020 19:52 | Pain | Mild | 21 | 0 | 02JUL2020 9:15 |
| | | 23JUL2020 19:52 | Tenderness | Mild | 21 | 0 | 02JUL2020 9:15 |
| | | 24JUL2020 19:48 | Pain | Mild | 22 | 1 | 02JUL2020 9:15 |
| Program: Lsaf_locR_1.sas (Page 11 of 30) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 20172 | 24JUL2020 19:48 | Tenderness | Mild | 22 | 1 | 02JUL2020 9:15 |
| | 20173 | 03JUL2020 20:12 | Pain | Mild | 1 | | 02JUL2020 10:30 |
| | 20174 | 06JUL2020 20:00 | Pain | Mild | 0 | | 06JUL2020 11:33 |
| | | 06JUL2020 20:00 | Tenderness | Moderate | 0 | | 06JUL2020 11:33 |
| | | 07JUL2020 21:30 | Pain | Mild | 1 | | 06JUL2020 11:33 |
| | | 07JUL2020 21:30 | Tenderness | Moderate | 1 | | 06JUL2020 11:33 |
| | | 08JUL2020 20:20 | Pain | Mild | 2 | | 06JUL2020 11:33 |
| | | 08JUL2020 20:20 | Tenderness | Moderate | 2 | | 06JUL2020 11:33 |
| | | 28JUL2020 11:20 | Pain | Mild | 22 | 1 | 06JUL2020 11:33 |
| | | 28JUL2020 11:20 | Tenderness | Mild | 22 | 1 | 06JUL2020 11:33 |
| | 20175 | 06JUL2020 20:01 | Pain | Mild | 0 | | 06JUL2020 9:30 |
| | | 06JUL2020 20:01 | Tenderness | Moderate | 0 | | 06JUL2020 9:30 |
| | | 07JUL2020 20:10 | Pain | Mild | 1 | | 06JUL2020 9:30 |
| | | 07JUL2020 20:10 | Tenderness | Mild | 1 | | 06JUL2020 9:30 |
| | | 08JUL2020 20:02 | Pain | Mild | 2 | | 06JUL2020 9:30 |
| | | 08JUL2020 20:02 | Tenderness | Mild | 2 | | 06JUL2020 9:30 |
| | | 27JUL2020 19:58 | Pain | Mild | 21 | 0 | 06JUL2020 9:30 |
| | | 27JUL2020 19:58 | Tenderness | Moderate | 21 | 0 | 06JUL2020 9:30 |
| Program: Lsaf_locR_1.sas (Page 12 of 30) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|---------------|--|-------------------------|-----------------|---------------------|---|---|---------------------------------|-----------------|
| 20 µg Younger | 20175 | 28JUL2020 20:00 | Pain | Mild | 22 | 1 | 06JUL2020 9:30 | |
| | | 28JUL2020 20:00 | Tenderness | Mild | 22 | 1 | 06JUL2020 9:30 | |
| | 20177 | 06JUL2020 20:31 | Tenderness | Mild | 0 | | 06JUL2020 11:03 | |
| | | 07JUL2020 20:45 | Tenderness | Mild | 1 | | 06JUL2020 11:03 | |
| | | 27JUL2020 20:20 | Pain | Mild | 21 | 0 | 06JUL2020 11:03 | |
| | | 27JUL2020 20:20 | Tenderness | Mild | 21 | 0 | 06JUL2020 11:03 | |
| | | 28JUL2020 20:15 | Pain | Mild | 22 | 1 | 06JUL2020 11:03 | |
| | | 28JUL2020 20:15 | Tenderness | Mild | 22 | 1 | 06JUL2020 11:03 | |
| | | 20178 | 06JUL2020 18:30 | Pain | Mild | 0 | | 06JUL2020 10:33 |
| | 20179 | 06JUL2020 20:45 | Pain | Mild | 0 | | 06JUL2020 10:00 | |
| | | 06JUL2020 20:45 | Tenderness | Mild | 0 | | 06JUL2020 10:00 | |
| | | 07JUL2020 20:45 | Pain | Mild | 1 | | 06JUL2020 10:00 | |
| | | 07JUL2020 20:45 | Tenderness | Mild | 1 | | 06JUL2020 10:00 | |
| | | 08JUL2020 20:45 | Pain | Mild | 2 | | 06JUL2020 10:00 | |
| | | 08JUL2020 20:45 | Tenderness | Mild | 2 | | 06JUL2020 10:00 | |
| | | 29JUL2020 20:20 | Pain | Mild | 23 | 0 | 06JUL2020 10:00 | |
| | | 29JUL2020 20:20 | Tenderness | Mild | 23 | 0 | 06JUL2020 10:00 | |
| | | 30JUL2020 20:20 | Pain | Mild | 24 | 1 | 06JUL2020 10:00 | |
| | Program: Lsaf_locR_1.sas (Page 13 of 30) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 20179 | 30JUL2020 20:20 | Tenderness | Mild | 24 | 1 | 06JUL2020 10:00 |
| | | 31JUL2020 20:20 | Pain | Mild | 25 | 2 | 06JUL2020 10:00 |
| | | 31JUL2020 20:20 | Tenderness | Mild | 25 | 2 | 06JUL2020 10:00 |
| | 20180 | 13JUL2020 21:00 | Tenderness | Mild | 0 | | 13JUL2020 10:00 |
| | | 14JUL2020 22:15 | Tenderness | Mild | 1 | | 13JUL2020 10:00 |
| | | 03AUG2020 21:30 | Pain | Mild | 21 | 0 | 13JUL2020 10:00 |
| | | 03AUG2020 21:30 | Tenderness | Mild | 21 | 0 | 13JUL2020 10:00 |
| | | 04AUG2020 21:00 | Pain | Mild | 22 | 1 | 13JUL2020 10:00 |
| | | 04AUG2020 21:00 | Tenderness | Mild | 22 | 1 | 13JUL2020 10:00 |
| | | 05AUG2020 21:30 | Pain | Mild | 23 | 2 | 13JUL2020 10:00 |
| | | 05AUG2020 21:30 | Tenderness | Mild | 23 | 2 | 13JUL2020 10:00 |
| | | 06AUG2020 21:30 | Pain | Mild | 24 | 3 | 13JUL2020 10:00 |
| | | 06AUG2020 21:30 | Tenderness | Mild | 24 | 3 | 13JUL2020 10:00 |
| | 20183 | 13JUL2020 22:30 | Pain | Mild | 0 | | 13JUL2020 10:30 |
| | | 13JUL2020 22:30 | Tenderness | Mild | 0 | | 13JUL2020 10:30 |
| | | 14JUL2020 22:30 | Pain | Moderate | 1 | | 13JUL2020 10:30 |
| | | 14JUL2020 22:30 | Tenderness | Moderate | 1 | | 13JUL2020 10:30 |
| | | 15JUL2020 22:30 | Pain | Mild | 2 | | 13JUL2020 10:30 |
| Program: Lsaf_locR_1.sas (Page 14 of 30) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 20183 | 15JUL2020 22:30 | Tenderness | Mild | 2 | | 13JUL2020 10:30 |
| | | 16JUL2020 22:30 | Pain | Mild | 3 | | 13JUL2020 10:30 |
| | | 16JUL2020 22:30 | Tenderness | Mild | 3 | | 13JUL2020 10:30 |
| | | 04AUG2020 22:00 | Pain | Moderate | 22 | 1 | 13JUL2020 10:30 |
| | | 04AUG2020 22:00 | Tenderness | Moderate | 22 | 1 | 13JUL2020 10:30 |
| | | 05AUG2020 22:00 | Pain | Mild | 23 | 2 | 13JUL2020 10:30 |
| | | 05AUG2020 22:00 | Tenderness | Mild | 23 | 2 | 13JUL2020 10:30 |
| | | 06AUG2020 22:00 | Pain | Mild | 24 | 3 | 13JUL2020 10:30 |
| | | 06AUG2020 22:00 | Tenderness | Mild | 24 | 3 | 13JUL2020 10:30 |
| | | 07AUG2020 22:00 | Pain | Mild | 25 | 4 | 13JUL2020 10:30 |
| | | 07AUG2020 22:00 | Tenderness | Mild | 25 | 4 | 13JUL2020 10:30 |
| | | 08AUG2020 22:00 | Tenderness | Mild | 26 | 5 | 13JUL2020 10:30 |
| | | 09AUG2020 22:00 | Tenderness | Mild | 27 | 6 | 13JUL2020 10:30 |
| 30 µg Younger | 20127 | 22JUN2020 19:46 | Pain | Mild | 0 | | 22JUN2020 8:30 |
| | | 22JUN2020 19:46 | Tenderness | Mild | 0 | | 22JUN2020 8:30 |
| | | 23JUN2020 19:55 | Pain | Mild | 1 | | 22JUN2020 8:30 |
| | | 23JUN2020 19:55 | Tenderness | Mild | 1 | | 22JUN2020 8:30 |
| | | 24JUN2020 19:50 | Pain | Mild | 2 | | 22JUN2020 8:30 |
| Program: Lsaf_locR_1.sas (Page 15 of 30) | | | | | | | |

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Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|-----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 20127 | 24JUN2020 19:50 | Tenderness | Mild | 2 | | 22JUN2020 8:30 |
| | | 25JUN2020 19:40 | Pain | Mild | 3 | | 22JUN2020 8:30 |
| | | 25JUN2020 19:40 | Tenderness | Mild | 3 | | 22JUN2020 8:30 |
| | | 26JUN2020 19:35 | Pain | Mild | 4 | | 22JUN2020 8:30 |
| | | 26JUN2020 19:35 | Tenderness | Mild | 4 | | 22JUN2020 8:30 |
| | | 27JUN2020 19:30 | Tenderness | Mild | 5 | | 22JUN2020 8:30 |
| | | 14JUL2020 19:40 | Pain | Mild | 22 | 0 | 22JUN2020 8:30 |
| | | 14JUL2020 19:40 | Tenderness | Mild | 22 | 0 | 22JUN2020 8:30 |
| | | 15JUL2020 19:45 | Pain | Mild | 23 | 1 | 22JUN2020 8:30 |
| | | 15JUL2020 19:45 | Tenderness | Mild | 23 | 1 | 22JUN2020 8:30 |
| | 16JUL2020 19:50 | Pain | Mild | 24 | 2 | 22JUN2020 8:30 | |
| | 16JUL2020 19:50 | Tenderness | Mild | 24 | 2 | 22JUN2020 8:30 | |
| | 17JUL2020 19:40 | Tenderness | Mild | 25 | 3 | 22JUN2020 8:30 | |
| | 20128 | 15JUL2020 21:30 | Pain | Mild | 22 | 1 | 23JUN2020 10:00 |
| | | 15JUL2020 21:30 | Tenderness | Mild | 22 | 1 | 23JUN2020 10:00 |
| 20134 | 25JUN2020 20:00 | Pain | Mild | 0 | | 25JUN2020 9:00 | |
| | 25JUN2020 20:00 | Tenderness | Mild | 0 | | 25JUN2020 9:00 | |
| | 25JUN2020 20:00 | Induration/Swelling | Mild | 0 | | 25JUN2020 9:00 | |

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Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|---------------|--|-------------------------|---------------------|---------------------|---|---|---------------------------------|--|
| 30 µg Younger | 20134 | 15JUL2020 20:00 | Tenderness | Mild | 20 | 0 | 25JUN2020 9:00 | |
| | | 16JUL2020 7:30 | Pain | Mild | 21 | 1 | 25JUN2020 9:00 | |
| | | 16JUL2020 7:30 | Tenderness | Mild | 21 | 1 | 25JUN2020 9:00 | |
| | | 16JUL2020 7:30 | Induration/Swelling | Mild | 21 | 1 | 25JUN2020 9:00 | |
| | | 17JUL2020 20:33 | Tenderness | Mild | 22 | 2 | 25JUN2020 9:00 | |
| | | 17JUL2020 20:33 | Induration/Swelling | Mild | 22 | 2 | 25JUN2020 9:00 | |
| | 20137 | 23JUN2020 20:16 | Tenderness | Moderate | 0 | | 23JUN2020 10:30 | |
| | | 24JUN2020 20:30 | Tenderness | Mild | 1 | | 23JUN2020 10:30 | |
| | | 15JUL2020 20:30 | Tenderness | Mild | 22 | 1 | 23JUN2020 10:30 | |
| | | 16JUL2020 20:30 | Tenderness | Mild | 23 | 2 | 23JUN2020 10:30 | |
| | 20138 | 25JUN2020 22:05 | Pain | Moderate | 0 | | 25JUN2020 11:30 | |
| | | 25JUN2020 22:05 | Tenderness | Moderate | 0 | | 25JUN2020 11:30 | |
| | | 25JUN2020 22:05 | Induration/Swelling | Mild | 0 | | 25JUN2020 11:30 | |
| | | 26JUN2020 21:03 | Pain | Mild | 1 | | 25JUN2020 11:30 | |
| | | 26JUN2020 21:03 | Tenderness | Mild | 1 | | 25JUN2020 11:30 | |
| | | 26JUN2020 21:03 | Induration/Swelling | Mild | 1 | | 25JUN2020 11:30 | |
| | | 15JUL2020 20:55 | Pain | Mild | 20 | 0 | 25JUN2020 11:30 | |
| | | 15JUL2020 20:55 | Tenderness | Mild | 20 | 0 | 25JUN2020 11:30 | |
| | Program: Lsaf_locR_1.sas (Page 17 of 30) | | | | | | | |

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Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|-----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 20143 | 25JUN2020 21:30 | Tenderness | Mild | 0 | | 25JUN2020 9:30 |
| | | 26JUN2020 21:10 | Tenderness | Mild | 1 | | 25JUN2020 9:30 |
| | | 27JUN2020 22:13 | Tenderness | Mild | 2 | | 25JUN2020 9:30 |
| | | 15JUL2020 21:15 | Pain | Mild | 20 | 0 | 25JUN2020 9:30 |
| | | 15JUL2020 21:15 | Tenderness | Mild | 20 | 0 | 25JUN2020 9:30 |
| | | 16JUL2020 10:35 | Pain | Mild | 21 | 1 | 25JUN2020 9:30 |
| | | 16JUL2020 10:35 | Tenderness | Mild | 21 | 1 | 25JUN2020 9:30 |
| | | 17JUL2020 22:05 | Pain | Mild | 22 | 2 | 25JUN2020 9:30 |
| | | 17JUL2020 22:05 | Tenderness | Mild | 22 | 2 | 25JUN2020 9:30 |
| | 18JUL2020 20:35 | Tenderness | Mild | 23 | 3 | 25JUN2020 9:30 | |
| | 20144 | 25JUN2020 20:00 | Tenderness | Mild | 0 | | 25JUN2020 11:00 |
| | | 26JUN2020 20:00 | Pain | Mild | 1 | | 25JUN2020 11:00 |
| | | 26JUN2020 20:00 | Tenderness | Mild | 1 | | 25JUN2020 11:00 |
| | | 16JUL2020 20:00 | Pain | Mild | 21 | 1 | 25JUN2020 11:00 |
| | | 16JUL2020 20:00 | Tenderness | Mild | 21 | 1 | 25JUN2020 11:00 |
| | 20145 | 25JUN2020 20:00 | Pain | Mild | 0 | | 25JUN2020 10:00 |
| | | 25JUN2020 20:00 | Tenderness | Mild | 0 | | 25JUN2020 10:00 |
| | | 26JUN2020 21:45 | Pain | Mild | 1 | | 25JUN2020 10:00 |
| Program: Lsaf_locR_1.sas (Page 18 of 30) | | | | | | | |

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Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|---------------|--|-------------------------|---------------------|---------------------|---|---|---------------------------------|--|
| 30 µg Younger | 20145 | 26JUN2020 21:45 | Tenderness | Mild | 1 | | 25JUN2020 10:00 | |
| | | 27JUN2020 23:00 | Pain | Mild | 2 | | 25JUN2020 10:00 | |
| | | 27JUN2020 23:00 | Tenderness | Mild | 2 | | 25JUN2020 10:00 | |
| | | 15JUL2020 20:00 | Tenderness | Mild | 20 | 0 | 25JUN2020 10:00 | |
| | | 15JUL2020 20:00 | Induration/Swelling | Mild | 20 | 0 | 25JUN2020 10:00 | |
| | | 16JUL2020 18:17 | Tenderness | Mild | 21 | 1 | 25JUN2020 10:00 | |
| | | 16JUL2020 18:17 | Induration/Swelling | Mild | 21 | 1 | 25JUN2020 10:00 | |
| | | 17JUL2020 22:40 | Tenderness | Mild | 22 | 2 | 25JUN2020 10:00 | |
| | 20149 | 22JUN2020 18:00 | Pain | Mild | 0 | | 22JUN2020 9:00 | |
| | | 22JUN2020 18:00 | Tenderness | Mild | 0 | | 22JUN2020 9:00 | |
| | | 23JUN2020 19:00 | Pain | Mild | 1 | | 22JUN2020 9:00 | |
| | | 14JUL2020 20:00 | Pain | Mild | 22 | 0 | 22JUN2020 9:00 | |
| | | 14JUL2020 20:00 | Tenderness | Mild | 22 | 0 | 22JUN2020 9:00 | |
| | | 15JUL2020 7:00 | Pain | Mild | 23 | 1 | 22JUN2020 9:00 | |
| | | 15JUL2020 7:00 | Tenderness | Mild | 23 | 1 | 22JUN2020 9:00 | |
| | 20150 | 23JUN2020 20:00 | Pain | Mild | 0 | | 23JUN2020 9:00 | |
| | | 23JUN2020 20:00 | Tenderness | Moderate | 0 | | 23JUN2020 9:00 | |
| | | 24JUN2020 17:11 | Pain | Mild | 1 | | 23JUN2020 9:00 | |
| | Program: Lsaf_locR_1.sas (Page 19 of 30) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 20150 | 24JUN2020 17:11 | Tenderness | Moderate | 1 | | 23JUN2020 9:00 |
| | | 25JUN2020 21:03 | Pain | Mild | 2 | | 23JUN2020 9:00 |
| | | 25JUN2020 21:03 | Tenderness | Mild | 2 | | 23JUN2020 9:00 |
| | | 14JUL2020 14:55 | Pain | Mild | 21 | 0 | 23JUN2020 9:00 |
| | | 14JUL2020 14:55 | Tenderness | Mild | 21 | 0 | 23JUN2020 9:00 |
| | | 15JUL2020 15:25 | Pain | Mild | 22 | 1 | 23JUN2020 9:00 |
| | | 15JUL2020 15:25 | Tenderness | Mild | 22 | 1 | 23JUN2020 9:00 |
| | | 15JUL2020 15:25 | Erythema/Redness | Mild | 22 | 1 | 23JUN2020 9:00 |
| | | 17JUL2020 18:00 | Tenderness | Mild | 24 | 3 | 23JUN2020 9:00 |
| | 20155 | 24JUN2020 20:36 | Pain | Mild | 1 | | 23JUN2020 9:30 |
| | | 24JUN2020 20:36 | Tenderness | Mild | 1 | | 23JUN2020 9:30 |
| | | 15JUL2020 20:00 | Pain | Mild | 22 | 1 | 23JUN2020 9:30 |
| | | 15JUL2020 20:00 | Tenderness | Mild | 22 | 1 | 23JUN2020 9:30 |
| | | 16JUL2020 20:00 | Pain | Mild | 23 | 2 | 23JUN2020 9:30 |
| 16JUL2020 20:00 | | Tenderness | Mild | 23 | 2 | 23JUN2020 9:30 | |
| 10 µg Older | 10261 | 14AUG2020 19:30 | Tenderness | Mild | 0 | | 14AUG2020 8:30 |
| | | 15AUG2020 19:36 | Tenderness | Mild | 1 | | 14AUG2020 8:30 |
| | | 04SEP2020 19:20 | Tenderness | Mild | 21 | 0 | 14AUG2020 8:30 |
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Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|-------------|--|-------------------------|---------------------|---------------------|---|---|---------------------------------|--|
| 10 µg Older | 10261 | 05SEP2020 19:23 | Tenderness | Mild | 22 | 1 | 14AUG2020 8:30 | |
| | | 06SEP2020 19:20 | Tenderness | Mild | 23 | 2 | 14AUG2020 8:30 | |
| | 10263 | 04SEP2020 20:20 | Pain | Mild | 21 | 0 | 14AUG2020 10:51 | |
| | 10265 | 18AUG2020 21:00 | Tenderness | Mild | 0 | | 18AUG2020 8:40 | |
| | 10267 | 19AUG2020 20:10 | Tenderness | Mild | 1 | | 18AUG2020 9:10 | |
| | | 08SEP2020 21:10 | Tenderness | Mild | 21 | 0 | 18AUG2020 9:10 | |
| | | 09SEP2020 21:50 | Tenderness | Moderate | 22 | 1 | 18AUG2020 9:10 | |
| | | 10SEP2020 21:40 | Tenderness | Mild | 23 | 2 | 18AUG2020 9:10 | |
| | | 11SEP2020 21:05 | Tenderness | Mild | 24 | 3 | 18AUG2020 9:10 | |
| | 10268 | 09SEP2020 19:00 | Pain | Severe | 22 | 1 | 18AUG2020 9:40 | |
| | | 09SEP2020 19:00 | Tenderness | Mild | 22 | 1 | 18AUG2020 9:40 | |
| | | 09SEP2020 19:00 | Induration/Swelling | Mild | 22 | 1 | 18AUG2020 9:40 | |
| | | 10SEP2020 19:00 | Induration/Swelling | Mild | 23 | 2 | 18AUG2020 9:40 | |
| | 10269 | 18AUG2020 19:37 | Pain | Mild | 0 | | 18AUG2020 10:10 | |
| | | 19AUG2020 19:43 | Pain | Mild | 1 | | 18AUG2020 10:10 | |
| | | 20AUG2020 20:00 | Pain | Mild | 2 | | 18AUG2020 10:10 | |
| | | 09SEP2020 | Pain | Mild | 22 | 1 | 18AUG2020 10:10 | |
| | | 09SEP2020 | Tenderness | Mild | 22 | 1 | 18AUG2020 10:10 | |
| | Program: Lsaf_locR_1.sas (Page 21 of 30) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|------------------|---------------------|---|---|---------------------------------|
| 10 µg Older | 10269 | 10SEP2020 | Pain | Mild | 23 | 2 | 18AUG2020 10:10 |
| | | 10SEP2020 | Tenderness | Mild | 23 | 2 | 18AUG2020 10:10 |
| | | 11SEP2020 | Pain | Mild | 24 | 3 | 18AUG2020 10:10 |
| | | 11SEP2020 | Tenderness | Mild | 24 | 3 | 18AUG2020 10:10 |
| | | 12SEP2020 | Pain | Mild | 25 | 4 | 18AUG2020 10:10 |
| | | 12SEP2020 | Tenderness | Mild | 25 | 4 | 18AUG2020 10:10 |
| | | 13SEP2020 | Pain | Mild | 26 | 5 | 18AUG2020 10:10 |
| | | 13SEP2020 | Tenderness | Mild | 26 | 5 | 18AUG2020 10:10 |
| | | 14SEP2020 | Pain | Mild | 27 | 6 | 18AUG2020 10:10 |
| | 14SEP2020 | Tenderness | Mild | 27 | 6 | 18AUG2020 10:10 | |
| | 10275 | 20AUG2020 21:50 | Pain | Mild | 0 | | 20AUG2020 8:20 |
| | | 20AUG2020 21:50 | Tenderness | Mild | 0 | | 20AUG2020 8:20 |
| | | 20AUG2020 21:50 | Erythema/Redness | Mild | 0 | | 20AUG2020 8:20 |
| | | 21AUG2020 21:45 | Tenderness | Mild | 1 | | 20AUG2020 8:20 |
| | | 21AUG2020 21:45 | Erythema/Redness | Mild | 1 | | 20AUG2020 8:20 |
| | | 22AUG2020 11:15 | Tenderness | Mild | 2 | | 20AUG2020 8:20 |
| | | 22AUG2020 11:15 | Erythema/Redness | Mild | 2 | | 20AUG2020 8:20 |
| | 23AUG2020 9:25 | Tenderness | Mild | 3 | | 20AUG2020 8:20 | |
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Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|-----------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 10 µg Older | 10275 | 23AUG2020 9:25 | Erythema/Redness | Mild | 3 | | 20AUG2020 8:20 |
| | | 24AUG2020 8:25 | Erythema/Redness | Mild | 4 | | 20AUG2020 8:20 |
| | | 25AUG2020 22:00 | Tenderness | Mild | 5 | | 20AUG2020 8:20 |
| | | 25AUG2020 22:00 | Erythema/Redness | Mild | 5 | | 20AUG2020 8:20 |
| | | 26AUG2020 9:10 | Erythema/Redness | Mild | 6 | | 20AUG2020 8:20 |
| | | 10SEP2020 22:30 | Pain | Mild | 21 | 0 | 20AUG2020 8:20 |
| | | 10SEP2020 22:30 | Tenderness | Mild | 21 | 0 | 20AUG2020 8:20 |
| | | 10SEP2020 22:30 | Induration/Swelling | Mild | 21 | 0 | 20AUG2020 8:20 |
| | | 11SEP2020 22:30 | Tenderness | Mild | 22 | 1 | 20AUG2020 8:20 |
| | | 11SEP2020 22:30 | Induration/Swelling | Mild | 22 | 1 | 20AUG2020 8:20 |
| | 12SEP2020 19:30 | Induration/Swelling | Mild | 23 | 2 | 20AUG2020 8:20 | |
| | 10279 | 20AUG2020 21:15 | Tenderness | Moderate | 0 | | 20AUG2020 9:50 |
| | 10300 | 21AUG2020 20:43 | Tenderness | Moderate | 1 | | 20AUG2020 10:50 |
| | | 10SEP2020 | Erythema/Redness | Moderate | 21 | 0 | 20AUG2020 10:50 |
| | | 11SEP2020 20:05 | Erythema/Redness | Moderate | 22 | 1 | 20AUG2020 10:50 |
| | | 12SEP2020 20:15 | Erythema/Redness | Moderate | 23 | 2 | 20AUG2020 10:50 |
| 13SEP2020 20:45 | | Erythema/Redness | Moderate | 24 | 3 | 20AUG2020 10:50 | |
| | 14SEP2020 21:00 | Erythema/Redness | Moderate | 25 | 4 | 20AUG2020 10:50 | |
| Program: Lsaf_locR_1.sas (Page 23 of 30) | | | | | | | |

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Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-----------------|----------------|-------------------------|------------------|---------------------|---|---|---------------------------------|
| 10 µg Older | 10300 | 15SEP2020 22:00 | Erythema/Redness | Moderate | 26 | 5 | 20AUG2020 10:50 |
| | | 16SEP2020 21:00 | Erythema/Redness | Moderate | 27 | 6 | 20AUG2020 10:50 |
| 20 µg Older | 20208 | 25AUG2020 22:00 | Pain | Moderate | 0 | | 25AUG2020 9:00 |
| | | 25AUG2020 22:00 | Tenderness | Moderate | 0 | | 25AUG2020 9:00 |
| | | 26AUG2020 22:00 | Pain | Mild | 1 | | 25AUG2020 9:00 |
| | | 26AUG2020 22:00 | Tenderness | Mild | 1 | | 25AUG2020 9:00 |
| | | 27AUG2020 22:00 | Pain | Mild | 2 | | 25AUG2020 9:00 |
| | | 14SEP2020 22:00 | Pain | Mild | 20 | 0 | 25AUG2020 9:00 |
| | | 14SEP2020 22:00 | Tenderness | Mild | 20 | 0 | 25AUG2020 9:00 |
| | | 15SEP2020 22:00 | Tenderness | Mild | 21 | 1 | 25AUG2020 9:00 |
| | 20214 | 27AUG2020 19:45 | Pain | Mild | 1 | | 26AUG2020 9:00 |
| | | 27AUG2020 19:45 | Tenderness | Mild | 1 | | 26AUG2020 9:00 |
| | | 14SEP2020 19:00 | Pain | Mild | 19 | 0 | 26AUG2020 9:00 |
| | | 14SEP2020 19:00 | Tenderness | Mild | 19 | 0 | 26AUG2020 9:00 |
| | | 15SEP2020 19:00 | Pain | Mild | 20 | 1 | 26AUG2020 9:00 |
| | | 15SEP2020 19:00 | Tenderness | Mild | 20 | 1 | 26AUG2020 9:00 |
| | 20215 | 01SEP2020 20:00 | Tenderness | Mild | 0 | | 01SEP2020 8:30 |
| 02SEP2020 20:00 | | Tenderness | Mild | 1 | | 01SEP2020 8:30 | |

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Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-----------------|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 20 µg Older | 20215 | 22SEP2020 20:00 | Pain | Mild | 21 | 0 | 01SEP2020 8:30 |
| | | 22SEP2020 20:00 | Tenderness | Mild | 21 | 0 | 01SEP2020 8:30 |
| | | 23SEP2020 20:00 | Pain | Mild | 22 | 1 | 01SEP2020 8:30 |
| | | 23SEP2020 20:00 | Tenderness | Mild | 22 | 1 | 01SEP2020 8:30 |
| | 20216 | 25AUG2020 22:00 | Tenderness | Moderate | 0 | | 25AUG2020 8:00 |
| | | 26AUG2020 22:00 | Tenderness | Mild | 1 | | 25AUG2020 8:00 |
| | | 14SEP2020 22:00 | Pain | Mild | 20 | 0 | 25AUG2020 8:00 |
| | | 14SEP2020 22:00 | Tenderness | Mild | 20 | 0 | 25AUG2020 8:00 |
| | 20221 | 01SEP2020 20:00 | Pain | Mild | 0 | | 01SEP2020 9:30 |
| | | 01SEP2020 20:00 | Tenderness | Moderate | 0 | | 01SEP2020 9:30 |
| | | 02SEP2020 20:00 | Pain | Mild | 1 | | 01SEP2020 9:30 |
| | | 02SEP2020 20:00 | Tenderness | Moderate | 1 | | 01SEP2020 9:30 |
| | | 03SEP2020 20:00 | Tenderness | Mild | 2 | | 01SEP2020 9:30 |
| | 20223 | 27AUG2020 21:00 | Pain | Mild | 1 | | 26AUG2020 10:30 |
| | 20224 | 22SEP2020 21:00 | Pain | Mild | 21 | 0 | 01SEP2020 8:00 |
| | | 22SEP2020 21:00 | Tenderness | Mild | 21 | 0 | 01SEP2020 8:00 |
| 23SEP2020 21:15 | | Pain | Mild | 22 | 1 | 01SEP2020 8:00 | |
| 23SEP2020 21:15 | | Tenderness | Mild | 22 | 1 | 01SEP2020 8:00 | |

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Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 20 µg Older | 20225 | 14SEP2020 19:50 | Erythema/Redness | Mild | 19 | 0 | 26AUG2020 10:00 |
| | | 14SEP2020 19:50 | Induration/Swelling | Mild | 19 | 0 | 26AUG2020 10:00 |
| | 20226 | 01SEP2020 21:30 | Pain | Mild | 0 | | 01SEP2020 10:00 |
| | | 01SEP2020 21:30 | Tenderness | Mild | 0 | | 01SEP2020 10:00 |
| | | 02SEP2020 21:20 | Pain | Mild | 1 | | 01SEP2020 10:00 |
| | | 02SEP2020 21:20 | Tenderness | Mild | 1 | | 01SEP2020 10:00 |
| | | 22SEP2020 21:20 | Pain | Mild | 21 | 0 | 01SEP2020 10:00 |
| | | 22SEP2020 21:20 | Tenderness | Mild | 21 | 0 | 01SEP2020 10:00 |
| | 20229 | 01SEP2020 20:30 | Tenderness | Mild | 0 | | 01SEP2020 9:00 |
| | | 02SEP2020 21:00 | Tenderness | Mild | 1 | | 01SEP2020 9:00 |
| | | 22SEP2020 20:00 | Pain | Mild | 21 | 0 | 01SEP2020 9:00 |
| | | 22SEP2020 20:00 | Tenderness | Moderate | 21 | 0 | 01SEP2020 9:00 |
| | | 23SEP2020 20:00 | Pain | Mild | 22 | 1 | 01SEP2020 9:00 |
| | | 23SEP2020 20:00 | Tenderness | Moderate | 22 | 1 | 01SEP2020 9:00 |
| | 20233 | 02SEP2020 20:00 | Tenderness | Mild | 1 | | 01SEP2020 10:30 |
| 30 µg Older | 10272 | 24SEP2020 21:00 | Pain | Moderate | 20 | 0 | 04SEP2020 8:20 |
| | | 24SEP2020 21:00 | Tenderness | Mild | 20 | 0 | 04SEP2020 8:20 |
| | | 25SEP2020 21:00 | Pain | Severe | 21 | 1 | 04SEP2020 8:20 |
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Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|-----------------|-------------------------|---------------------|---------------------|---|---|---------------------------------|
| 30 µg Older | 10272 | 25SEP2020 21:00 | Tenderness | Moderate | 21 | 1 | 04SEP2020 8:20 |
| | | 25SEP2020 21:00 | Erythema/Redness | Mild | 21 | 1 | 04SEP2020 8:20 |
| | | 25SEP2020 21:00 | Induration/Swelling | Mild | 21 | 1 | 04SEP2020 8:20 |
| | | 26SEP2020 21:00 | Pain | Mild | 22 | 2 | 04SEP2020 8:20 |
| | | 26SEP2020 21:00 | Tenderness | Mild | 22 | 2 | 04SEP2020 8:20 |
| | | 26SEP2020 21:00 | Erythema/Redness | Mild | 22 | 2 | 04SEP2020 8:20 |
| | | 26SEP2020 21:00 | Induration/Swelling | Mild | 22 | 2 | 04SEP2020 8:20 |
| | | 27SEP2020 21:00 | Pain | Mild | 23 | 3 | 04SEP2020 8:20 |
| | | 27SEP2020 21:00 | Tenderness | Mild | 23 | 3 | 04SEP2020 8:20 |
| | | 28SEP2020 21:00 | Pain | Mild | 24 | 4 | 04SEP2020 8:20 |
| | 28SEP2020 21:00 | Tenderness | Mild | 24 | 4 | 04SEP2020 8:20 | |
| | 10303 | 05SEP2020 20:00 | Pain | Mild | 1 | | 04SEP2020 8:52 |
| | | 05SEP2020 20:00 | Tenderness | Mild | 1 | | 04SEP2020 8:52 |
| | | 06SEP2020 20:00 | Pain | Mild | 2 | | 04SEP2020 8:52 |
| | | 06SEP2020 20:00 | Tenderness | Mild | 2 | | 04SEP2020 8:52 |
| | | 07SEP2020 20:00 | Pain | Mild | 3 | | 04SEP2020 8:52 |
| | | 07SEP2020 20:00 | Tenderness | Mild | 3 | | 04SEP2020 8:52 |
| 24SEP2020 20:00 | | Pain | Mild | 20 | 0 | 04SEP2020 8:52 | |
| Program: Lsaf_locR_1.sas (Page 27 of 30) | | | | | | | |

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Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-----------------|----------------|-------------------------|----------------|---------------------|---|---|---------------------------------|
| 30 µg Older | 10303 | 24SEP2020 20:00 | Tenderness | Mild | 20 | 0 | 04SEP2020 8:52 |
| | | 25SEP2020 20:00 | Pain | Mild | 21 | 1 | 04SEP2020 8:52 |
| | | 25SEP2020 20:00 | Tenderness | Mild | 21 | 1 | 04SEP2020 8:52 |
| | 10305 | 04SEP2020 21:00 | Pain | Mild | 0 | | 04SEP2020 9:20 |
| | | 04SEP2020 21:00 | Tenderness | Mild | 0 | | 04SEP2020 9:20 |
| | | 05SEP2020 21:00 | Tenderness | Mild | 1 | | 04SEP2020 9:20 |
| | 10306 | 01SEP2020 20:00 | Pain | Mild | 0 | | 01SEP2020 9:20 |
| | | 01SEP2020 20:00 | Tenderness | Mild | 0 | | 01SEP2020 9:20 |
| | | 02SEP2020 20:00 | Tenderness | Mild | 1 | | 01SEP2020 9:20 |
| | | 03SEP2020 20:00 | Tenderness | Mild | 2 | | 01SEP2020 9:20 |
| | | 22SEP2020 20:00 | Tenderness | Mild | 21 | 0 | 01SEP2020 9:20 |
| | | 23SEP2020 20:00 | Tenderness | Mild | 22 | 1 | 01SEP2020 9:20 |
| | | 24SEP2020 20:00 | Tenderness | Mild | 23 | 2 | 01SEP2020 9:20 |
| | 10308 | 25SEP2020 18:10 | Pain | Moderate | 21 | 1 | 04SEP2020 9:50 |
| | 10310 | 02SEP2020 20:00 | Pain | Mild | 0 | | 02SEP2020 9:10 |
| | | 02SEP2020 20:00 | Tenderness | Mild | 0 | | 02SEP2020 9:10 |
| | | 23SEP2020 20:00 | Pain | Moderate | 21 | 0 | 02SEP2020 9:10 |
| 23SEP2020 20:00 | | Tenderness | Moderate | 21 | 0 | 02SEP2020 9:10 | |

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Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|-------------|--|-------------------------|----------------|---------------------|---|---|---------------------------------|--|
| 30 µg Older | 10310 | 24SEP2020 20:00 | Pain | Moderate | 22 | 1 | 02SEP2020 9:10 | |
| | | 24SEP2020 20:00 | Tenderness | Mild | 22 | 1 | 02SEP2020 9:10 | |
| | | 25SEP2020 20:00 | Tenderness | Mild | 23 | 2 | 02SEP2020 9:10 | |
| | 10314 | 02SEP2020 21:00 | Tenderness | Mild | 0 | | 02SEP2020 9:40 | |
| | | 23SEP2020 21:00 | Pain | Mild | 21 | 0 | 02SEP2020 9:40 | |
| | | 23SEP2020 21:00 | Tenderness | Mild | 21 | 0 | 02SEP2020 9:40 | |
| | | 24SEP2020 21:00 | Pain | Moderate | 22 | 1 | 02SEP2020 9:40 | |
| | 10316 | 01SEP2020 18:00 | Tenderness | Mild | 0 | | 01SEP2020 8:30 | |
| | | 02SEP2020 0:00 | Tenderness | Mild | 1 | | 01SEP2020 8:30 | |
| | | 22SEP2020 22:30 | Tenderness | Moderate | 21 | 0 | 01SEP2020 8:30 | |
| | | 23SEP2020 23:15 | Pain | Mild | 22 | 1 | 01SEP2020 8:30 | |
| | 10319 | 04SEP2020 20:30 | Pain | Mild | 0 | | 04SEP2020 10:22 | |
| | | 04SEP2020 20:30 | Tenderness | Mild | 0 | | 04SEP2020 10:22 | |
| | | 05SEP2020 20:30 | Pain | Mild | 1 | | 04SEP2020 10:22 | |
| | | 05SEP2020 20:30 | Tenderness | Mild | 1 | | 04SEP2020 10:22 | |
| | | 24SEP2020 20:30 | Pain | Mild | 20 | 0 | 04SEP2020 10:22 | |
| | | 24SEP2020 20:30 | Tenderness | Mild | 20 | 0 | 04SEP2020 10:22 | |
| | | 25SEP2020 20:30 | Tenderness | Mild | 21 | 1 | 04SEP2020 10:22 | |
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Listing 16.2.3-1.1-3: Listing of solicited local reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Local reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-------------|--|-------------------------|------------------|---------------------|---|---|---------------------------------|
| 30 µg Older | 10319 | 26SEP2020 20:30 | Tenderness | Mild | 22 | 2 | 04SEP2020 10:22 |
| | 10323 | 04SEP2020 21:15 | Pain | Mild | 0 | | 04SEP2020 10:50 |
| | | 05SEP2020 21:05 | Pain | Mild | 1 | | 04SEP2020 10:50 |
| | | 05SEP2020 21:05 | Tenderness | Moderate | 1 | | 04SEP2020 10:50 |
| | | 25SEP2020 20:15 | Tenderness | Mild | 21 | 1 | 04SEP2020 10:50 |
| | | 25SEP2020 20:15 | Erythema/Redness | Mild | 21 | 1 | 04SEP2020 10:50 |
| | | 26SEP2020 20:50 | Tenderness | Mild | 22 | 2 | 04SEP2020 10:50 |
| | | 26SEP2020 20:50 | Erythema/Redness | Mild | 22 | 2 | 04SEP2020 10:50 |
| | | 27SEP2020 22:20 | Erythema/Redness | Mild | 23 | 3 | 04SEP2020 10:50 |
| | | 28SEP2020 20:30 | Erythema/Redness | Mild | 24 | 4 | 04SEP2020 10:50 |
| | 10324 | 03SEP2020 20:10 | Pain | Mild | 1 | | 02SEP2020 10:10 |
| | | 23SEP2020 20:30 | Pain | Mild | 21 | 0 | 02SEP2020 10:10 |
| | | 24SEP2020 20:30 | Pain | Mild | 22 | 1 | 02SEP2020 10:10 |
| | Program: Lsaf_locR_1.sas (Page 30 of 30) | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-----------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 1 µg Younger | 20153 | 29JUN2020 21:30 | Fatigue | Mild | 0 | | 29JUN2020 8:10 |
| | | 20JUL2020 21:30 | Fatigue | Mild | 21 | 0 | 29JUN2020 8:10 |
| | 20157 | 01JUL2020 21:00 | Loss of Appetite | Mild | 2 | | 29JUN2020 9:10 |
| | 20158 | 14JUL2020 19:30 | Myalgia | Mild | 1 | | 13JUL2020 8:00 |
| | | 03AUG2020 19:30 | Fatigue | Mild | 21 | 0 | 13JUL2020 8:00 |
| | 20160 | 29JUN2020 21:51 | Fatigue | Mild | 0 | | 29JUN2020 8:40 |
| | | 30JUN2020 22:00 | Headache | Mild | 1 | | 29JUN2020 8:40 |
| | | 30JUN2020 22:00 | Fatigue | Mild | 1 | | 29JUN2020 8:40 |
| | | 30JUN2020 22:00 | Myalgia | Moderate | 1 | | 29JUN2020 8:40 |
| | | 30JUN2020 22:00 | Arthralgia | Moderate | 1 | | 29JUN2020 8:40 |
| | | 30JUN2020 22:00 | Chills | Mild | 1 | | 29JUN2020 8:40 |
| | | 30JUN2020 22:00 | Malaise | Moderate | 1 | | 29JUN2020 8:40 |
| | | 01JUL2020 21:45 | Nausea | Mild | 2 | | 29JUN2020 8:40 |
| | | 01JUL2020 21:45 | Diarrhea | Mild | 2 | | 29JUN2020 8:40 |
| | | 01JUL2020 21:45 | Headache | Mild | 2 | | 29JUN2020 8:40 |
| | | 01JUL2020 21:45 | Fatigue | Mild | 2 | | 29JUN2020 8:40 |
| 01JUL2020 21:45 | Myalgia | Mild | 2 | | 29JUN2020 8:40 | | |
| 01JUL2020 21:45 | Arthralgia | Mild | 2 | | 29JUN2020 8:40 | | |

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Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 1 µg Younger | 20160 | 01JUL2020 21:45 | Chills | Mild | 2 | | 29JUN2020 8:40 |
| | | 01JUL2020 21:45 | Malaise | Mild | 2 | | 29JUN2020 8:40 |
| | | 03JUL2020 22:19 | Headache | Mild | 4 | | 29JUN2020 8:40 |
| | | 03JUL2020 22:19 | Fatigue | Mild | 4 | | 29JUN2020 8:40 |
| | | 03JUL2020 22:19 | Malaise | Mild | 4 | | 29JUN2020 8:40 |
| | | 04JUL2020 21:43 | Headache | Mild | 5 | | 29JUN2020 8:40 |
| | | 04JUL2020 21:43 | Fatigue | Mild | 5 | | 29JUN2020 8:40 |
| | | 04JUL2020 21:43 | Malaise | Mild | 5 | | 29JUN2020 8:40 |
| | | 05JUL2020 21:53 | Headache | Mild | 6 | | 29JUN2020 8:40 |
| | | 05JUL2020 21:53 | Fatigue | Mild | 6 | | 29JUN2020 8:40 |
| | | 05JUL2020 21:53 | Malaise | Mild | 6 | | 29JUN2020 8:40 |
| | | 06JUL2020 22:03 | Headache | Mild | 7 | | 29JUN2020 8:40 |
| | | 06JUL2020 22:03 | Fatigue | Mild | 7 | | 29JUN2020 8:40 |
| | | 06JUL2020 22:03 | Malaise | Mild | 7 | | 29JUN2020 8:40 |
| | | 07JUL2020 8:25 | Headache | Mild | 8 | | 29JUN2020 8:40 |
| | | 07JUL2020 8:25 | Fatigue | Mild | 8 | | 29JUN2020 8:40 |
| | | 07JUL2020 8:25 | Malaise | Mild | 8 | | 29JUN2020 8:40 |
| | 20163 | 29JUN2020 19:40 | Fatigue | Mild | 0 | | 29JUN2020 9:40 |
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Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

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Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 1 µg Younger | 20164 | 13JUL2020 19:00 | Headache | Mild | 0 | | 13JUL2020 9:30 |
| | | 13JUL2020 19:00 | Fatigue | Mild | 0 | | 13JUL2020 9:30 |
| | | 13JUL2020 19:00 | Malaise | Mild | 0 | | 13JUL2020 9:30 |
| | | 03AUG2020 19:50 | Fatigue | Moderate | 21 | 0 | 13JUL2020 9:30 |
| | 20166 | 29JUN2020 20:00 | Fatigue | Mild | 0 | | 29JUN2020 10:10 |
| | | 20JUL2020 20:00 | Fatigue | Mild | 21 | 0 | 29JUN2020 10:10 |
| | | 24JUL2020 20:00 | Diarrhea | Mild | 25 | 4 | 29JUN2020 10:10 |
| | | 26JUL2020 20:00 | Diarrhea | Mild | 27 | 6 | 29JUN2020 10:10 |
| | 20181 | 28JUL2020 20:10 | Headache | Mild | 0 | | 28JUL2020 9:00 |
| | | 29JUL2020 22:00 | Malaise | Mild | 1 | | 28JUL2020 9:00 |
| | | 30JUL2020 21:30 | Malaise | Mild | 2 | | 28JUL2020 9:00 |
| | 20188 | 31JUL2020 16:00 | Fatigue | Mild | 3 | | 28JUL2020 8:00 |
| | | 31JUL2020 16:00 | Malaise | Mild | 3 | | 28JUL2020 8:00 |
| 3 µg Younger | 20176 | 29JUL2020 21:00 | Headache | Mild | 0 | | 29JUL2020 9:00 |
| | | 29JUL2020 21:00 | Fatigue | Mild | 0 | | 29JUL2020 9:00 |
| | | 30JUL2020 21:00 | Headache | Mild | 1 | | 29JUL2020 9:00 |
| | | 30JUL2020 21:00 | Fatigue | Mild | 1 | | 29JUL2020 9:00 |
| | | 30JUL2020 21:00 | Malaise | Mild | 1 | | 29JUL2020 9:00 |

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Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 3 µg Younger | 20176 | 18AUG2020 21:00 | Nausea | Mild | 20 | 0 | 29JUL2020 9:00 |
| | | 18AUG2020 21:00 | Headache | Moderate | 20 | 0 | 29JUL2020 9:00 |
| | | 18AUG2020 21:00 | Malaise | Mild | 20 | 0 | 29JUL2020 9:00 |
| | | 25AUG2020 21:00 | Headache | Mild | 27 | 7 | 29JUL2020 9:00 |
| | 20185 | 30JUL2020 19:57 | Headache | Moderate | 1 | | 29JUL2020 8:00 |
| | | 30JUL2020 19:57 | Fatigue | Mild | 1 | | 29JUL2020 8:00 |
| | | 30JUL2020 19:57 | Arthralgia | Mild | 1 | | 29JUL2020 8:00 |
| | | 30JUL2020 19:57 | Malaise | Mild | 1 | | 29JUL2020 8:00 |
| | 20192 | 28JUL2020 18:00 | Fatigue | Mild | 0 | | 28JUL2020 10:00 |
| | | 30JUL2020 19:00 | Headache | Mild | 2 | | 28JUL2020 10:00 |
| | | 30JUL2020 19:00 | Fatigue | Mild | 2 | | 28JUL2020 10:00 |
| | | 30JUL2020 19:00 | Malaise | Mild | 2 | | 28JUL2020 10:00 |
| | | 31JUL2020 20:00 | Fatigue | Mild | 3 | | 28JUL2020 10:00 |
| | 20193 | 29JUL2020 22:50 | Fatigue | Mild | 0 | | 29JUL2020 8:30 |
| | 20194 | 29JUL2020 23:00 | Fatigue | Mild | 0 | | 29JUL2020 9:30 |
| | 20197 | 29JUL2020 19:41 | Headache | Mild | 1 | | 28JUL2020 9:30 |
| | | 02AUG2020 19:58 | Fatigue | Mild | 5 | | 28JUL2020 9:30 |
| | 20201 | 06AUG2020 21:00 | Headache | Moderate | 0 | | 06AUG2020 8:36 |
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Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 3 µg Younger | 20201 | 06AUG2020 21:00 | Myalgia | Mild | 0 | | 06AUG2020 8:36 |
| | | 07AUG2020 23:00 | Headache | Mild | 1 | | 06AUG2020 8:36 |
| | | 07AUG2020 23:00 | Malaise | Mild | 1 | | 06AUG2020 8:36 |
| | | 09AUG2020 23:00 | Headache | Mild | 3 | | 06AUG2020 8:36 |
| | | 10AUG2020 23:00 | Headache | Mild | 4 | | 06AUG2020 8:36 |
| | | 11AUG2020 23:00 | Headache | Mild | 5 | | 06AUG2020 8:36 |
| | | 12AUG2020 9:03 | Headache | Mild | 6 | | 06AUG2020 8:36 |
| | | 26AUG2020 21:00 | Myalgia | Mild | 20 | 0 | 06AUG2020 8:36 |
| | | 27AUG2020 21:00 | Myalgia | Mild | 21 | 1 | 06AUG2020 8:36 |
| | | 27AUG2020 21:00 | Malaise | Mild | 21 | 1 | 06AUG2020 8:36 |
| | | 31AUG2020 23:00 | Diarrhea | Mild | 25 | 5 | 06AUG2020 8:36 |
| | | 01SEP2020 22:30 | Headache | Mild | 26 | 6 | 06AUG2020 8:36 |
| | | 02SEP2020 23:00 | Diarrhea | Mild | 27 | 7 | 06AUG2020 8:36 |
| | | 02SEP2020 23:00 | Headache | Mild | 27 | 7 | 06AUG2020 8:36 |
| | | 02SEP2020 23:00 | Fatigue | Mild | 27 | 7 | 06AUG2020 8:36 |
| | | 02SEP2020 23:00 | Loss of Appetite | Mild | 27 | 7 | 06AUG2020 8:36 |
| | | 02SEP2020 23:00 | Malaise | Mild | 27 | 7 | 06AUG2020 8:36 |
| 03SEP2020 10:05 | Headache | Mild | 28 | 8 | 06AUG2020 8:36 | | |
| Program: Lsaf_sysR_1.sas (Page 5 of 30) | | | | | | | |

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Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 3 µg Younger | 20203 | 31JUL2020 19:28 | Headache | Mild | 0 | | 31JUL2020 9:37 |
| | | 31JUL2020 19:28 | Myalgia | Mild | 0 | | 31JUL2020 9:37 |
| | | 01AUG2020 21:54 | Headache | Mild | 1 | | 31JUL2020 9:37 |
| | | 04AUG2020 21:17 | Headache | Mild | 4 | | 31JUL2020 9:37 |
| | 20204 | 31JUL2020 21:14 | Myalgia | Mild | 0 | | 31JUL2020 10:07 |
| | | 01AUG2020 21:37 | Diarrhea | Mild | 1 | | 31JUL2020 10:07 |
| | | 01AUG2020 21:37 | Malaise | Mild | 1 | | 31JUL2020 10:07 |
| 10 µg Younger | 20101 | 17JUN2020 22:00 | Fatigue | Moderate | 1 | | 16JUN2020 8:45 |
| | | 17JUN2020 22:00 | Myalgia | Mild | 1 | | 16JUN2020 8:45 |
| | | 17JUN2020 22:00 | Arthralgia | Mild | 1 | | 16JUN2020 8:45 |
| | 20102 | 16JUN2020 20:00 | Nausea | Mild | 0 | | 16JUN2020 7:45 |
| | 20103 | 15JUN2020 20:10 | Fatigue | Mild | 0 | | 15JUN2020 9:22 |
| | | 17JUN2020 20:18 | Headache | Moderate | 2 | | 15JUN2020 9:22 |
| | | 20JUN2020 20:31 | Nausea | Mild | 5 | | 15JUN2020 9:22 |
| | | 06JUL2020 21:01 | Headache | Moderate | 21 | 0 | 15JUN2020 9:22 |
| | | 06JUL2020 21:01 | Fatigue | Moderate | 21 | 0 | 15JUN2020 9:22 |
| | | 06JUL2020 21:01 | Myalgia | Severe | 21 | 0 | 15JUN2020 9:22 |
| 06JUL2020 21:01 | | Arthralgia | Moderate | 21 | 0 | 15JUN2020 9:22 | |
| Program: Lsaf_sysR_1.sas (Page 6 of 30) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---|-----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 10 µg Younger | 20103 | 06JUL2020 21:01 | Chills | Moderate | 21 | 0 | 15JUN2020 9:22 |
| | | 06JUL2020 21:01 | Malaise | Severe | 21 | 0 | 15JUN2020 9:22 |
| | 20104 | 17JUN2020 19:45 | Fatigue | Mild | 1 | | 16JUN2020 9:45 |
| | | 18JUN2020 20:00 | Fatigue | Mild | 2 | | 16JUN2020 9:45 |
| | | 19JUN2020 19:43 | Headache | Mild | 3 | | 16JUN2020 9:45 |
| | | 19JUN2020 19:43 | Fatigue | Mild | 3 | | 16JUN2020 9:45 |
| | | 20JUN2020 19:47 | Fatigue | Mild | 4 | | 16JUN2020 9:45 |
| | | 20JUN2020 19:47 | Arthralgia | Mild | 4 | | 16JUN2020 9:45 |
| | | 08JUL2020 20:45 | Headache | Moderate | 22 | 1 | 16JUN2020 9:45 |
| | | 10JUL2020 20:45 | Fatigue | Mild | 24 | 3 | 16JUN2020 9:45 |
| | 20105 | 16JUN2020 21:12 | Headache | Moderate | 0 | | 16JUN2020 10:47 |
| | | 06JUL2020 20:02 | Diarrhea | Mild | 20 | 0 | 16JUN2020 10:47 |
| | | 07JUL2020 20:00 | Headache | Moderate | 21 | 1 | 16JUN2020 10:47 |
| | | 07JUL2020 20:00 | Fatigue | Moderate | 21 | 1 | 16JUN2020 10:47 |
| | | 07JUL2020 20:00 | Arthralgia | Moderate | 21 | 1 | 16JUN2020 10:47 |
| | | 07JUL2020 20:00 | Chills | Moderate | 21 | 1 | 16JUN2020 10:47 |
| | | 07JUL2020 20:00 | Malaise | Moderate | 21 | 1 | 16JUN2020 10:47 |
| | 07JUL2020 20:00 | Fever | Mild | 21 | 1 | 16JUN2020 10:47 | |
| Program: Lsaf_sysR_1.sas (Page 7 of 30) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|---------------|---|-------------------------|-------------------|---------------------|---|---|---------------------------------|--|
| 10 µg Younger | 20110 | 16JUN2020 20:15 | Myalgia | Mild | 0 | | 16JUN2020 11:48 | |
| | | 16JUN2020 20:15 | Arthralgia | Mild | 0 | | 16JUN2020 11:48 | |
| | | 07JUL2020 20:30 | Fatigue | Mild | 21 | 0 | 16JUN2020 11:48 | |
| | | 08JUL2020 20:00 | Headache | Mild | 22 | 1 | 16JUN2020 11:48 | |
| | | 08JUL2020 20:00 | Fatigue | Mild | 22 | 1 | 16JUN2020 11:48 | |
| | | 08JUL2020 20:00 | Myalgia | Mild | 22 | 1 | 16JUN2020 11:48 | |
| | | 08JUL2020 20:00 | Arthralgia | Mild | 22 | 1 | 16JUN2020 11:48 | |
| | | 08JUL2020 20:00 | Malaise | Mild | 22 | 1 | 16JUN2020 11:48 | |
| | | 09JUL2020 20:00 | Headache | Mild | 23 | 2 | 16JUN2020 11:48 | |
| | 20111 | 18JUN2020 21:30 | Fatigue | Mild | 0 | | 18JUN2020 11:00 | |
| | | 19JUN2020 22:00 | Fatigue | Mild | 1 | | 18JUN2020 11:00 | |
| | | 19JUN2020 22:00 | Chills | Mild | 1 | | 18JUN2020 11:00 | |
| | | 20JUN2020 21:30 | Fatigue | Mild | 2 | | 18JUN2020 11:00 | |
| | | 15JUL2020 21:00 | Headache | Mild | 27 | 0 | 18JUN2020 11:00 | |
| | 20114 | 18JUN2020 22:00 | Nausea | Mild | 0 | | 18JUN2020 10:00 | |
| | | 18JUN2020 22:00 | Headache | Moderate | 0 | | 18JUN2020 10:00 | |
| | | 18JUN2020 22:00 | Fatigue | Mild | 0 | | 18JUN2020 10:00 | |
| | | 18JUN2020 22:00 | Loss of Appetite | Mild | 0 | | 18JUN2020 10:00 | |
| | Program: Lsaf_sysR_1.sas (Page 8 of 30) | | | | | | | |

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Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 10 µg Younger | 20114 | 18JUN2020 22:00 | Malaise | Mild | 0 | | 18JUN2020 10:00 |
| | | 19JUN2020 22:00 | Headache | Mild | 1 | | 18JUN2020 10:00 |
| | 20116 | 18JUN2020 22:04 | Nausea | Mild | 0 | | 18JUN2020 12:00 |
| | | 18JUN2020 22:04 | Headache | Mild | 0 | | 18JUN2020 12:00 |
| | 20117 | 20JUN2020 19:00 | Nausea | Mild | 2 | | 18JUN2020 10:30 |
| | | 20JUN2020 19:00 | Headache | Mild | 2 | | 18JUN2020 10:30 |
| | | 09JUL2020 20:00 | Headache | Mild | 21 | 0 | 18JUN2020 10:30 |
| | 20118 | 20JUN2020 20:15 | Fatigue | Mild | 2 | | 18JUN2020 12:30 |
| | | 09JUL2020 20:55 | Fatigue | Mild | 21 | 0 | 18JUN2020 12:30 |
| | | 10JUL2020 21:00 | Fatigue | Mild | 22 | 1 | 18JUN2020 12:30 |
| | | 10JUL2020 21:00 | Myalgia | Mild | 22 | 1 | 18JUN2020 12:30 |
| | | 10JUL2020 21:00 | Arthralgia | Mild | 22 | 1 | 18JUN2020 12:30 |
| | | 11JUL2020 19:35 | Headache | Mild | 23 | 2 | 18JUN2020 12:30 |
| | | 11JUL2020 19:35 | Fatigue | Mild | 23 | 2 | 18JUN2020 12:30 |
| | 20121 | 18JUN2020 22:00 | Myalgia | Mild | 0 | | 18JUN2020 11:30 |
| 19JUN2020 22:00 | | Myalgia | Mild | 1 | | 18JUN2020 11:30 | |
| 20JUN2020 22:00 | | Myalgia | Mild | 2 | | 18JUN2020 11:30 | |
| 20 µg Younger | 20156 | 03JUL2020 21:00 | Headache | Moderate | 1 | | 02JUL2020 10:00 |
| Program: Lsaf_sysR_1.sas (Page 9 of 30) | | | | | | | |

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Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|-----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 20156 | 03JUL2020 21:00 | Fatigue | Moderate | 1 | | 02JUL2020 10:00 |
| | | 03JUL2020 21:00 | Myalgia | Moderate | 1 | | 02JUL2020 10:00 |
| | | 03JUL2020 21:00 | Arthralgia | Moderate | 1 | | 02JUL2020 10:00 |
| | | 03JUL2020 21:00 | Malaise | Moderate | 1 | | 02JUL2020 10:00 |
| | | 06JUL2020 22:00 | Fatigue | Mild | 4 | | 02JUL2020 10:00 |
| | | 07JUL2020 22:00 | Fatigue | Mild | 5 | | 02JUL2020 10:00 |
| | | 23JUL2020 23:00 | Headache | Moderate | 21 | 0 | 02JUL2020 10:00 |
| | | 23JUL2020 23:00 | Myalgia | Moderate | 21 | 0 | 02JUL2020 10:00 |
| | | 23JUL2020 23:00 | Arthralgia | Moderate | 21 | 0 | 02JUL2020 10:00 |
| | | 23JUL2020 23:00 | Chills | Mild | 21 | 0 | 02JUL2020 10:00 |
| | | 23JUL2020 23:00 | Malaise | Moderate | 21 | 0 | 02JUL2020 10:00 |
| | | 24JUL2020 23:30 | Headache | Mild | 22 | 1 | 02JUL2020 10:00 |
| | | 20159 | 01JUL2020 20:13 | Fatigue | Mild | 0 | |
| | 02JUL2020 20:10 | | Headache | Mild | 1 | | 01JUL2020 8:00 |
| | 02JUL2020 20:10 | | Fatigue | Mild | 1 | | 01JUL2020 8:00 |
| | 04JUL2020 20:05 | | Fatigue | Mild | 3 | | 01JUL2020 8:00 |
| | 22JUL2020 20:00 | | Fatigue | Mild | 21 | 0 | 01JUL2020 8:00 |
| | 23JUL2020 20:00 | | Fatigue | Mild | 22 | 1 | 01JUL2020 8:00 |

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Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|---------------|----------------|--|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 20159 | 23JUL2020 20:00 | Myalgia | Mild | 22 | 1 | 01JUL2020 8:00 |
| | | 23JUL2020 20:00 | Chills | Moderate | 22 | 1 | 01JUL2020 8:00 |
| | | 23JUL2020 20:00 | Loss of Appetite | Mild | 22 | 1 | 01JUL2020 8:00 |
| | | 23JUL2020 20:00 | Malaise | Mild | 22 | 1 | 01JUL2020 8:00 |
| | 20168 | 01JUL2020 21:00 | Fatigue | Mild | 0 | | 01JUL2020 9:00 |
| | | 03JUL2020 22:15 | Headache | Moderate | 2 | | 01JUL2020 9:00 |
| | | 03JUL2020 22:15 | Fatigue | Mild | 2 | | 01JUL2020 9:00 |
| | | 04JUL2020 21:50 | Headache | Moderate | 3 | | 01JUL2020 9:00 |
| | | 04JUL2020 21:50 | Fatigue | Mild | 3 | | 01JUL2020 9:00 |
| | | 05JUL2020 22:00 | Headache | Moderate | 4 | | 01JUL2020 9:00 |
| | | 05JUL2020 22:00 | Fatigue | Mild | 4 | | 01JUL2020 9:00 |
| | | 06JUL2020 22:05 | Headache | Moderate | 5 | | 01JUL2020 9:00 |
| | | 06JUL2020 22:05 | Fatigue | Mild | 5 | | 01JUL2020 9:00 |
| | | 07JUL2020 22:00 | Headache | Moderate | 6 | | 01JUL2020 9:00 |
| | | 07JUL2020 22:00 | Fatigue | Mild | 6 | | 01JUL2020 9:00 |
| | | 22JUL2020 22:00 | Headache | Mild | 21 | 0 | 01JUL2020 9:00 |
| | | 22JUL2020 22:00 | Myalgia | Mild | 21 | 0 | 01JUL2020 9:00 |
| | | 23JUL2020 23:00 | Headache | Mild | 22 | 1 | 01JUL2020 9:00 |
| | | Program: Lsaf_sysR_1.sas (Page 11 of 30) | | | | | |

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Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|-----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 20168 | 23JUL2020 23:00 | Myalgia | Mild | 22 | 1 | 01JUL2020 9:00 |
| | | 24JUL2020 21:30 | Headache | Mild | 23 | 2 | 01JUL2020 9:00 |
| | | 24JUL2020 21:30 | Myalgia | Mild | 23 | 2 | 01JUL2020 9:00 |
| | 20172 | 02JUL2020 19:40 | Headache | Mild | 0 | | 02JUL2020 9:15 |
| | | 02JUL2020 19:40 | Fatigue | Mild | 0 | | 02JUL2020 9:15 |
| | | 03JUL2020 19:50 | Headache | Severe | 1 | | 02JUL2020 9:15 |
| | | 03JUL2020 19:50 | Fatigue | Mild | 1 | | 02JUL2020 9:15 |
| | | 06JUL2020 19:47 | Fatigue | Mild | 4 | | 02JUL2020 9:15 |
| | | 07JUL2020 19:45 | Headache | Mild | 5 | | 02JUL2020 9:15 |
| | | 23JUL2020 19:52 | Headache | Mild | 21 | 0 | 02JUL2020 9:15 |
| | | 23JUL2020 19:52 | Fatigue | Moderate | 21 | 0 | 02JUL2020 9:15 |
| | | 24JUL2020 19:48 | Headache | Moderate | 22 | 1 | 02JUL2020 9:15 |
| | | 24JUL2020 19:48 | Fatigue | Mild | 22 | 1 | 02JUL2020 9:15 |
| | 20173 | 23JUL2020 21:45 | Headache | Mild | 21 | 0 | 02JUL2020 10:30 |
| | 20175 | 06JUL2020 20:05 | Fatigue | Mild | 0 | | 06JUL2020 9:30 |
| | 20177 | 28JUL2020 20:17 | Headache | Mild | 22 | 1 | 06JUL2020 11:03 |
| | | 28JUL2020 20:17 | Myalgia | Mild | 22 | 1 | 06JUL2020 11:03 |
| 20178 | 06JUL2020 18:30 | Fatigue | Mild | 0 | | 06JUL2020 10:33 | |
| Program: Lsaf_sysR_1.sas (Page 12 of 30) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

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Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 20178 | 08JUL2020 18:30 | Diarrhea | Mild | 2 | | 06JUL2020 10:33 |
| | | 09JUL2020 18:30 | Diarrhea | Mild | 3 | | 06JUL2020 10:33 |
| | | 28JUL2020 18:30 | Diarrhea | Mild | 22 | 1 | 06JUL2020 10:33 |
| | | 29JUL2020 18:30 | Diarrhea | Mild | 23 | 2 | 06JUL2020 10:33 |
| | | 30JUL2020 18:00 | Diarrhea | Mild | 24 | 3 | 06JUL2020 10:33 |
| | | 31JUL2020 18:30 | Diarrhea | Mild | 25 | 4 | 06JUL2020 10:33 |
| | 20179 | 06JUL2020 20:45 | Fatigue | Mild | 0 | | 06JUL2020 10:00 |
| | | 07JUL2020 20:45 | Fatigue | Mild | 1 | | 06JUL2020 10:00 |
| | | 29JUL2020 20:20 | Nausea | Mild | 23 | 0 | 06JUL2020 10:00 |
| | | 29JUL2020 20:20 | Chills | Mild | 23 | 0 | 06JUL2020 10:00 |
| | | 29JUL2020 20:20 | Malaise | Mild | 23 | 0 | 06JUL2020 10:00 |
| | 20180 | 17JUL2020 21:30 | Diarrhea | Mild | 4 | | 13JUL2020 10:00 |
| | | 17JUL2020 21:30 | Fatigue | Mild | 4 | | 13JUL2020 10:00 |
| | | 04AUG2020 21:00 | Fatigue | Severe | 22 | 1 | 13JUL2020 10:00 |
| | | 04AUG2020 21:00 | Myalgia | Moderate | 22 | 1 | 13JUL2020 10:00 |
| | | 04AUG2020 21:00 | Chills | Severe | 22 | 1 | 13JUL2020 10:00 |
| | | 04AUG2020 21:00 | Fever | Mild | 22 | 1 | 13JUL2020 10:00 |
| | | 05AUG2020 21:30 | Fatigue | Moderate | 23 | 2 | 13JUL2020 10:00 |
| Program: Lsaf_sysR_1.sas (Page 13 of 30) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 20180 | 06AUG2020 21:30 | Fatigue | Moderate | 24 | 3 | 13JUL2020 10:00 |
| | | 07AUG2020 21:30 | Fatigue | Mild | 25 | 4 | 13JUL2020 10:00 |
| | 20183 | 14JUL2020 22:30 | Myalgia | Moderate | 1 | | 13JUL2020 10:30 |
| | | 14JUL2020 22:30 | Arthralgia | Moderate | 1 | | 13JUL2020 10:30 |
| | | 15JUL2020 22:30 | Myalgia | Mild | 2 | | 13JUL2020 10:30 |
| | | 15JUL2020 22:30 | Arthralgia | Mild | 2 | | 13JUL2020 10:30 |
| | | 16JUL2020 22:30 | Myalgia | Mild | 3 | | 13JUL2020 10:30 |
| | | 16JUL2020 22:30 | Arthralgia | Mild | 3 | | 13JUL2020 10:30 |
| | | 04AUG2020 22:00 | Headache | Mild | 22 | 1 | 13JUL2020 10:30 |
| | | 04AUG2020 22:00 | Fatigue | Mild | 22 | 1 | 13JUL2020 10:30 |
| | | 04AUG2020 22:00 | Myalgia | Moderate | 22 | 1 | 13JUL2020 10:30 |
| | | 04AUG2020 22:00 | Arthralgia | Moderate | 22 | 1 | 13JUL2020 10:30 |
| | | 04AUG2020 22:00 | Malaise | Mild | 22 | 1 | 13JUL2020 10:30 |
| | | 05AUG2020 22:00 | Myalgia | Mild | 23 | 2 | 13JUL2020 10:30 |
| | | 05AUG2020 22:00 | Arthralgia | Mild | 23 | 2 | 13JUL2020 10:30 |
| | | 06AUG2020 22:00 | Myalgia | Mild | 24 | 3 | 13JUL2020 10:30 |
| | | 06AUG2020 22:00 | Arthralgia | Mild | 24 | 3 | 13JUL2020 10:30 |
| | | 07AUG2020 22:00 | Myalgia | Mild | 25 | 4 | 13JUL2020 10:30 |
| Program: Lsaf_sysR_1.sas (Page 14 of 30) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Younger | 20183 | 07AUG2020 22:00 | Arthralgia | Mild | 25 | 4 | 13JUL2020 10:30 |
| | | 08AUG2020 22:00 | Myalgia | Mild | 26 | 5 | 13JUL2020 10:30 |
| | | 09AUG2020 22:00 | Myalgia | Mild | 27 | 6 | 13JUL2020 10:30 |
| 30 µg Younger | 20127 | 22JUN2020 19:46 | Fatigue | Mild | 0 | | 22JUN2020 8:30 |
| | | 23JUN2020 19:55 | Fatigue | Mild | 1 | | 22JUN2020 8:30 |
| | | 24JUN2020 19:50 | Fatigue | Mild | 2 | | 22JUN2020 8:30 |
| | | 25JUN2020 19:40 | Fatigue | Mild | 3 | | 22JUN2020 8:30 |
| | | 26JUN2020 19:35 | Fatigue | Mild | 4 | | 22JUN2020 8:30 |
| | | 27JUN2020 19:30 | Fatigue | Mild | 5 | | 22JUN2020 8:30 |
| | | 14JUL2020 19:30 | Fatigue | Mild | 22 | 0 | 22JUN2020 8:30 |
| | | 15JUL2020 19:35 | Fatigue | Mild | 23 | 1 | 22JUN2020 8:30 |
| | | 16JUL2020 19:50 | Fatigue | Mild | 24 | 2 | 22JUN2020 8:30 |
| | 20128 | 15JUL2020 21:30 | Chills | Mild | 22 | 1 | 23JUN2020 10:00 |
| | 20134 | 15JUL2020 20:00 | Fatigue | Mild | 20 | 0 | 25JUN2020 9:00 |
| | | 15JUL2020 20:00 | Myalgia | Mild | 20 | 0 | 25JUN2020 9:00 |
| | | 15JUL2020 20:00 | Arthralgia | Mild | 20 | 0 | 25JUN2020 9:00 |
| | | 15JUL2020 20:00 | Malaise | Mild | 20 | 0 | 25JUN2020 9:00 |
| | | 16JUL2020 7:30 | Fatigue | Mild | 21 | 1 | 25JUN2020 9:00 |
| Program: Lsaf_sysR_1.sas (Page 15 of 30) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 20134 | 16JUL2020 7:30 | Myalgia | Mild | 21 | 1 | 25JUN2020 9:00 |
| | | 16JUL2020 7:30 | Arthralgia | Mild | 21 | 1 | 25JUN2020 9:00 |
| | | 16JUL2020 7:30 | Malaise | Moderate | 21 | 1 | 25JUN2020 9:00 |
| | 20137 | 29JUN2020 20:30 | Headache | Mild | 6 | | 23JUN2020 10:30 |
| | 20138 | 25JUN2020 22:05 | Fatigue | Moderate | 0 | | 25JUN2020 11:30 |
| | | 25JUN2020 22:05 | Myalgia | Moderate | 0 | | 25JUN2020 11:30 |
| | | 25JUN2020 22:05 | Malaise | Moderate | 0 | | 25JUN2020 11:30 |
| | | 26JUN2020 21:03 | Fatigue | Moderate | 1 | | 25JUN2020 11:30 |
| | | 26JUN2020 21:03 | Myalgia | Mild | 1 | | 25JUN2020 11:30 |
| | | 26JUN2020 21:03 | Malaise | Moderate | 1 | | 25JUN2020 11:30 |
| | | 15JUL2020 20:55 | Myalgia | Mild | 20 | 0 | 25JUN2020 11:30 |
| | 20142 | 26JUN2020 19:03 | Nausea | Mild | 1 | | 25JUN2020 10:30 |
| | | 26JUN2020 19:03 | Headache | Mild | 1 | | 25JUN2020 10:30 |
| | | 26JUN2020 19:03 | Fatigue | Mild | 1 | | 25JUN2020 10:30 |
| | | 26JUN2020 19:03 | Chills | Mild | 1 | | 25JUN2020 10:30 |
| | | 26JUN2020 19:03 | Malaise | Mild | 1 | | 25JUN2020 10:30 |
| | | 16JUL2020 19:01 | Nausea | Severe | 21 | 1 | 25JUN2020 10:30 |
| 16JUL2020 19:01 | | Fatigue | Severe | 21 | 1 | 25JUN2020 10:30 | |
| Program: Lsaf_sysR_1.sas (Page 16 of 30) | | | | | | | |

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Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 20142 | 16JUL2020 19:01 | Myalgia | Moderate | 21 | 1 | 25JUN2020 10:30 |
| | | 16JUL2020 19:01 | Arthralgia | Severe | 21 | 1 | 25JUN2020 10:30 |
| | | 16JUL2020 19:01 | Chills | Severe | 21 | 1 | 25JUN2020 10:30 |
| | | 16JUL2020 19:01 | Malaise | Moderate | 21 | 1 | 25JUN2020 10:30 |
| | 20143 | 25JUN2020 21:30 | Headache | Mild | 0 | | 25JUN2020 9:30 |
| | | 25JUN2020 21:30 | Malaise | Mild | 0 | | 25JUN2020 9:30 |
| | | 15JUL2020 21:15 | Headache | Mild | 20 | 0 | 25JUN2020 9:30 |
| | | 15JUL2020 21:15 | Fatigue | Mild | 20 | 0 | 25JUN2020 9:30 |
| | | 15JUL2020 21:15 | Myalgia | Mild | 20 | 0 | 25JUN2020 9:30 |
| | | 15JUL2020 21:15 | Arthralgia | Mild | 20 | 0 | 25JUN2020 9:30 |
| | | 15JUL2020 21:15 | Malaise | Mild | 20 | 0 | 25JUN2020 9:30 |
| | | 16JUL2020 10:35 | Headache | Mild | 21 | 1 | 25JUN2020 9:30 |
| | | 16JUL2020 10:35 | Fatigue | Moderate | 21 | 1 | 25JUN2020 9:30 |
| | | 16JUL2020 10:35 | Myalgia | Severe | 21 | 1 | 25JUN2020 9:30 |
| | | 16JUL2020 10:35 | Arthralgia | Severe | 21 | 1 | 25JUN2020 9:30 |
| | | 16JUL2020 10:35 | Chills | Moderate | 21 | 1 | 25JUN2020 9:30 |
| | | 16JUL2020 10:35 | Malaise | Moderate | 21 | 1 | 25JUN2020 9:30 |
| | | 17JUL2020 22:05 | Myalgia | Mild | 22 | 2 | 25JUN2020 9:30 |
| Program: Lsaf_sysR_1.sas (Page 17 of 30) | | | | | | | |

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Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 20143 | 17JUL2020 22:05 | Arthralgia | Mild | 22 | 2 | 25JUN2020 9:30 |
| | 20144 | 26JUN2020 20:00 | Headache | Mild | 1 | | 25JUN2020 11:00 |
| | | 16JUL2020 20:00 | Headache | Mild | 21 | 1 | 25JUN2020 11:00 |
| | | 16JUL2020 20:00 | Fatigue | Mild | 21 | 1 | 25JUN2020 11:00 |
| | | 16JUL2020 20:00 | Chills | Mild | 21 | 1 | 25JUN2020 11:00 |
| | 20145 | 25JUN2020 20:00 | Nausea | Mild | 0 | | 25JUN2020 10:00 |
| | | 25JUN2020 20:00 | Headache | Mild | 0 | | 25JUN2020 10:00 |
| | | 25JUN2020 20:00 | Fatigue | Mild | 0 | | 25JUN2020 10:00 |
| | | 25JUN2020 20:00 | Myalgia | Mild | 0 | | 25JUN2020 10:00 |
| | | 25JUN2020 20:00 | Malaise | Mild | 0 | | 25JUN2020 10:00 |
| | | 26JUN2020 21:45 | Nausea | Mild | 1 | | 25JUN2020 10:00 |
| | | 26JUN2020 21:45 | Headache | Mild | 1 | | 25JUN2020 10:00 |
| | | 26JUN2020 21:45 | Fatigue | Mild | 1 | | 25JUN2020 10:00 |
| | | 26JUN2020 21:45 | Myalgia | Mild | 1 | | 25JUN2020 10:00 |
| | | 26JUN2020 21:45 | Malaise | Mild | 1 | | 25JUN2020 10:00 |
| | | 27JUN2020 23:00 | Nausea | Mild | 2 | | 25JUN2020 10:00 |
| 27JUN2020 23:00 | | Headache | Mild | 2 | | 25JUN2020 10:00 | |
| 27JUN2020 23:00 | Fatigue | Moderate | 2 | | 25JUN2020 10:00 | | |
| Program: Lsaf_sysR_1.sas (Page 18 of 30) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|-----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 20145 | 27JUN2020 23:00 | Malaise | Mild | 2 | | 25JUN2020 10:00 |
| | | 16JUL2020 18:17 | Headache | Moderate | 21 | 1 | 25JUN2020 10:00 |
| | | 16JUL2020 18:17 | Fatigue | Moderate | 21 | 1 | 25JUN2020 10:00 |
| | | 16JUL2020 18:17 | Arthralgia | Mild | 21 | 1 | 25JUN2020 10:00 |
| | | 16JUL2020 18:17 | Chills | Mild | 21 | 1 | 25JUN2020 10:00 |
| | | 16JUL2020 18:17 | Loss of Appetite | Mild | 21 | 1 | 25JUN2020 10:00 |
| | | 16JUL2020 18:17 | Malaise | Moderate | 21 | 1 | 25JUN2020 10:00 |
| | | 17JUL2020 22:40 | Headache | Mild | 22 | 2 | 25JUN2020 10:00 |
| | | 17JUL2020 22:40 | Fatigue | Mild | 22 | 2 | 25JUN2020 10:00 |
| | | 17JUL2020 22:40 | Arthralgia | Mild | 22 | 2 | 25JUN2020 10:00 |
| | 17JUL2020 22:40 | Malaise | Mild | 22 | 2 | 25JUN2020 10:00 | |
| | 20149 | 15JUL2020 7:00 | Headache | Moderate | 23 | 1 | 22JUN2020 9:00 |
| | | 15JUL2020 7:00 | Fatigue | Mild | 23 | 1 | 22JUN2020 9:00 |
| | | 15JUL2020 7:00 | Myalgia | Mild | 23 | 1 | 22JUN2020 9:00 |
| | | 15JUL2020 7:00 | Arthralgia | Moderate | 23 | 1 | 22JUN2020 9:00 |
| | | 15JUL2020 7:00 | Chills | Mild | 23 | 1 | 22JUN2020 9:00 |
| | | 15JUL2020 7:00 | Loss of Appetite | Moderate | 23 | 1 | 22JUN2020 9:00 |
| 15JUL2020 7:00 | | Malaise | Mild | 23 | 1 | 22JUN2020 9:00 | |
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Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 20149 | 16JUL2020 19:00 | Arthralgia | Mild | 24 | 2 | 22JUN2020 9:00 |
| | 20150 | 27JUN2020 14:06 | Diarrhea | Mild | 4 | | 23JUN2020 9:00 |
| | | 29JUN2020 18:47 | Fatigue | Mild | 6 | | 23JUN2020 9:00 |
| | | 14JUL2020 14:55 | Fatigue | Mild | 21 | 0 | 23JUN2020 9:00 |
| | | 15JUL2020 15:25 | Headache | Mild | 22 | 1 | 23JUN2020 9:00 |
| | | 15JUL2020 15:25 | Fatigue | Mild | 22 | 1 | 23JUN2020 9:00 |
| | | 15JUL2020 15:25 | Myalgia | Mild | 22 | 1 | 23JUN2020 9:00 |
| | | 15JUL2020 15:25 | Arthralgia | Mild | 22 | 1 | 23JUN2020 9:00 |
| | | 16JUL2020 22:20 | Fatigue | Mild | 23 | 2 | 23JUN2020 9:00 |
| | | 16JUL2020 22:20 | Myalgia | Mild | 23 | 2 | 23JUN2020 9:00 |
| | | 16JUL2020 22:20 | Arthralgia | Mild | 23 | 2 | 23JUN2020 9:00 |
| | | 17JUL2020 18:00 | Myalgia | Severe | 24 | 3 | 23JUN2020 9:00 |
| | | 17JUL2020 18:00 | Arthralgia | Severe | 24 | 3 | 23JUN2020 9:00 |
| | | 17JUL2020 18:00 | Malaise | Moderate | 24 | 3 | 23JUN2020 9:00 |
| | | 18JUL2020 21:30 | Fatigue | Severe | 25 | 4 | 23JUN2020 9:00 |
| | | 18JUL2020 21:30 | Myalgia | Severe | 25 | 4 | 23JUN2020 9:00 |
| | | 18JUL2020 21:30 | Arthralgia | Severe | 25 | 4 | 23JUN2020 9:00 |
| 18JUL2020 21:30 | Malaise | Severe | 25 | 4 | 23JUN2020 9:00 | | |
| Program: Lsaf_sysR_1.sas (Page 20 of 30) | | | | | | | |

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Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|-----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Younger | 20150 | 19JUL2020 16:00 | Fatigue | Moderate | 26 | 5 | 23JUN2020 9:00 |
| | | 19JUL2020 16:00 | Myalgia | Mild | 26 | 5 | 23JUN2020 9:00 |
| | | 19JUL2020 16:00 | Arthralgia | Mild | 26 | 5 | 23JUN2020 9:00 |
| | 20155 | 30JUN2020 10:02 | Diarrhea | Mild | 7 | | 23JUN2020 9:30 |
| 10 µg Older | 10263 | 04SEP2020 20:20 | Myalgia | Mild | 21 | 0 | 14AUG2020 10:51 |
| | 10267 | 18AUG2020 21:10 | Fatigue | Severe | 0 | | 18AUG2020 9:10 |
| | | 18AUG2020 21:10 | Myalgia | Moderate | 0 | | 18AUG2020 9:10 |
| | | 19AUG2020 20:10 | Fatigue | Moderate | 1 | | 18AUG2020 9:10 |
| | | 20AUG2020 16:30 | Fatigue | Mild | 2 | | 18AUG2020 9:10 |
| | | 21AUG2020 22:05 | Headache | Mild | 3 | | 18AUG2020 9:10 |
| | | 21AUG2020 22:05 | Fatigue | Moderate | 3 | | 18AUG2020 9:10 |
| | | 23AUG2020 22:30 | Headache | Mild | 5 | | 18AUG2020 9:10 |
| | | 23AUG2020 22:30 | Fatigue | Moderate | 5 | | 18AUG2020 9:10 |
| | | 08SEP2020 21:10 | Fatigue | Mild | 21 | 0 | 18AUG2020 9:10 |
| | | 09SEP2020 21:50 | Fatigue | Mild | 22 | 1 | 18AUG2020 9:10 |
| | 10SEP2020 21:40 | Fatigue | Mild | 23 | 2 | 18AUG2020 9:10 | |
| | 10268 | 18AUG2020 16:00 | Fatigue | Mild | 0 | | 18AUG2020 9:40 |
| 22AUG2020 16:00 | | Nausea | Mild | 4 | | 18AUG2020 9:40 | |
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Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-------------|--|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 10 µg Older | 10268 | 22AUG2020 16:00 | Fatigue | Mild | 4 | | 18AUG2020 9:40 |
| | | 22AUG2020 16:00 | Loss of Appetite | Mild | 4 | | 18AUG2020 9:40 |
| | | 22AUG2020 16:00 | Malaise | Mild | 4 | | 18AUG2020 9:40 |
| | | 23AUG2020 16:00 | Diarrhea | Mild | 5 | | 18AUG2020 9:40 |
| | | 23AUG2020 16:00 | Fatigue | Mild | 5 | | 18AUG2020 9:40 |
| | | 23AUG2020 16:00 | Arthralgia | Mild | 5 | | 18AUG2020 9:40 |
| | | 23AUG2020 16:00 | Loss of Appetite | Mild | 5 | | 18AUG2020 9:40 |
| | | 23AUG2020 16:00 | Malaise | Mild | 5 | | 18AUG2020 9:40 |
| | | 24AUG2020 16:00 | Fatigue | Mild | 6 | | 18AUG2020 9:40 |
| | | 24AUG2020 16:00 | Arthralgia | Mild | 6 | | 18AUG2020 9:40 |
| | | 24AUG2020 16:00 | Loss of Appetite | Mild | 6 | | 18AUG2020 9:40 |
| | | 24AUG2020 16:00 | Malaise | Mild | 6 | | 18AUG2020 9:40 |
| | 10275 | 20AUG2020 21:50 | Fatigue | Mild | 0 | | 20AUG2020 8:20 |
| | | 21AUG2020 21:20 | Fatigue | Mild | 1 | | 20AUG2020 8:20 |
| | | 22AUG2020 8:15 | Nausea | Mild | 2 | | 20AUG2020 8:20 |
| | | 22AUG2020 8:15 | Headache | Moderate | 2 | | 20AUG2020 8:20 |
| | | 22AUG2020 8:15 | Fatigue | Mild | 2 | | 20AUG2020 8:20 |
| | | 22AUG2020 8:15 | Malaise | Mild | 2 | | 20AUG2020 8:20 |
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Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|--|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 10 µg Older | 10275 | 26AUG2020 9:10 | Headache | Mild | 6 | | 20AUG2020 8:20 |
| | | 10SEP2020 22:30 | Headache | Moderate | 21 | 0 | 20AUG2020 8:20 |
| | | 10SEP2020 22:30 | Fatigue | Mild | 21 | 0 | 20AUG2020 8:20 |
| | | 11SEP2020 18:30 | Nausea | Mild | 22 | 1 | 20AUG2020 8:20 |
| | | 11SEP2020 18:30 | Headache | Moderate | 22 | 1 | 20AUG2020 8:20 |
| | | 11SEP2020 18:30 | Fatigue | Moderate | 22 | 1 | 20AUG2020 8:20 |
| | | 11SEP2020 18:30 | Myalgia | Moderate | 22 | 1 | 20AUG2020 8:20 |
| | | 11SEP2020 18:30 | Malaise | Moderate | 22 | 1 | 20AUG2020 8:20 |
| | | 13SEP2020 20:00 | Headache | Mild | 24 | 3 | 20AUG2020 8:20 |
| | | 13SEP2020 20:00 | Loss of Appetite | Moderate | 24 | 3 | 20AUG2020 8:20 |
| | 16SEP2020 9:15 | Headache | Mild | 27 | 6 | 20AUG2020 8:20 | |
| | 10300 | 10SEP2020 17:00 | Nausea | Severe | 21 | 0 | 20AUG2020 10:50 |
| | | 10SEP2020 17:00 | Headache | Moderate | 21 | 0 | 20AUG2020 10:50 |
| | | 10SEP2020 17:00 | Fatigue | Moderate | 21 | 0 | 20AUG2020 10:50 |
| 10SEP2020 17:00 | | Malaise | Severe | 21 | 0 | 20AUG2020 10:50 | |
| 20 µg Older | 20208 | 25AUG2020 22:00 | Headache | Moderate | 0 | | 25AUG2020 9:00 |
| | | 25AUG2020 22:00 | Fatigue | Mild | 0 | | 25AUG2020 9:00 |
| | | 26AUG2020 22:00 | Fatigue | Mild | 1 | | 25AUG2020 9:00 |
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Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-----------------|-----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Older | 20208 | 14SEP2020 22:00 | Headache | Mild | 20 | 0 | 25AUG2020 9:00 |
| | | 14SEP2020 22:00 | Fatigue | Mild | 20 | 0 | 25AUG2020 9:00 |
| | | 14SEP2020 22:00 | Myalgia | Mild | 20 | 0 | 25AUG2020 9:00 |
| | | 15SEP2020 22:00 | Headache | Mild | 21 | 1 | 25AUG2020 9:00 |
| | | 15SEP2020 22:00 | Fatigue | Mild | 21 | 1 | 25AUG2020 9:00 |
| | | 15SEP2020 22:00 | Myalgia | Mild | 21 | 1 | 25AUG2020 9:00 |
| | | 16SEP2020 22:00 | Headache | Mild | 22 | 2 | 25AUG2020 9:00 |
| | | 16SEP2020 22:00 | Fatigue | Mild | 22 | 2 | 25AUG2020 9:00 |
| | | 16SEP2020 22:00 | Myalgia | Mild | 22 | 2 | 25AUG2020 9:00 |
| | | 16SEP2020 22:00 | Loss of Appetite | Mild | 22 | 2 | 25AUG2020 9:00 |
| | | 17SEP2020 22:00 | Fatigue | Mild | 23 | 3 | 25AUG2020 9:00 |
| | 17SEP2020 22:00 | Loss of Appetite | Mild | 23 | 3 | 25AUG2020 9:00 | |
| | 20214 | 27AUG2020 19:45 | Headache | Mild | 1 | | 26AUG2020 9:00 |
| | 20215 | 22SEP2020 20:00 | Myalgia | Mild | 21 | 0 | 01SEP2020 8:30 |
| 23SEP2020 20:00 | | Myalgia | Mild | 22 | 1 | 01SEP2020 8:30 | |
| 20216 | 15SEP2020 22:00 | Fatigue | Mild | 21 | 1 | 25AUG2020 8:00 | |
| | 15SEP2020 22:00 | Chills | Mild | 21 | 1 | 25AUG2020 8:00 | |
| 20221 | 01SEP2020 20:00 | Fatigue | Mild | 0 | | 01SEP2020 9:30 | |

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Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|-------------|--|-------------------------|-------------------|---------------------|---|---|---------------------------------|--|
| 20 µg Older | 20221 | 02SEP2020 20:00 | Fatigue | Mild | 1 | | 01SEP2020 9:30 | |
| | 20224 | 22SEP2020 21:00 | Headache | Mild | 21 | 0 | 01SEP2020 8:00 | |
| | | 22SEP2020 21:00 | Fatigue | Mild | 21 | 0 | 01SEP2020 8:00 | |
| | | 22SEP2020 21:00 | Myalgia | Mild | 21 | 0 | 01SEP2020 8:00 | |
| | | 23SEP2020 20:30 | Headache | Moderate | 22 | 1 | 01SEP2020 8:00 | |
| | | 23SEP2020 20:30 | Fatigue | Moderate | 22 | 1 | 01SEP2020 8:00 | |
| | | 23SEP2020 20:30 | Myalgia | Moderate | 22 | 1 | 01SEP2020 8:00 | |
| | 20225 | 14SEP2020 19:50 | Headache | Mild | 19 | 0 | 26AUG2020 10:00 | |
| | | 14SEP2020 19:50 | Fatigue | Mild | 19 | 0 | 26AUG2020 10:00 | |
| | | 14SEP2020 19:50 | Myalgia | Mild | 19 | 0 | 26AUG2020 10:00 | |
| | | 14SEP2020 19:50 | Arthralgia | Mild | 19 | 0 | 26AUG2020 10:00 | |
| | | 14SEP2020 19:50 | Malaise | Mild | 19 | 0 | 26AUG2020 10:00 | |
| | | 15SEP2020 19:50 | Arthralgia | Mild | 20 | 1 | 26AUG2020 10:00 | |
| | 20226 | 28SEP2020 21:30 | Headache | Mild | 27 | 6 | 01SEP2020 10:00 | |
| | 20229 | 23SEP2020 20:00 | Fatigue | Mild | 22 | 1 | 01SEP2020 9:00 | |
| | 20233 | 02SEP2020 20:10 | Headache | Mild | 1 | | 01SEP2020 10:30 | |
| | | 02SEP2020 20:10 | Fatigue | Mild | 1 | | 01SEP2020 10:30 | |
| | | 02SEP2020 20:10 | Malaise | Mild | 1 | | 01SEP2020 10:30 | |
| | Program: Lsaf_sysR_1.sas (Page 25 of 30) | | | | | | | |

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Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-------------|----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 20 µg Older | 20233 | 03SEP2020 20:00 | Headache | Mild | 2 | | 01SEP2020 10:30 |
| | | 03SEP2020 20:00 | Fatigue | Mild | 2 | | 01SEP2020 10:30 |
| | | 22SEP2020 20:00 | Headache | Mild | 21 | 0 | 01SEP2020 10:30 |
| | | 22SEP2020 20:00 | Fatigue | Moderate | 21 | 0 | 01SEP2020 10:30 |
| | | 23SEP2020 19:00 | Headache | Mild | 22 | 1 | 01SEP2020 10:30 |
| | | 23SEP2020 19:00 | Fatigue | Mild | 22 | 1 | 01SEP2020 10:30 |
| | | 24SEP2020 19:00 | Fatigue | Mild | 23 | 2 | 01SEP2020 10:30 |
| 30 µg Older | 10272 | 05SEP2020 21:00 | Fatigue | Mild | 1 | | 04SEP2020 8:20 |
| | | 24SEP2020 21:00 | Headache | Mild | 20 | 0 | 04SEP2020 8:20 |
| | | 24SEP2020 21:00 | Fatigue | Moderate | 20 | 0 | 04SEP2020 8:20 |
| | | 24SEP2020 21:00 | Chills | Severe | 20 | 0 | 04SEP2020 8:20 |
| | | 24SEP2020 21:00 | Loss of Appetite | Mild | 20 | 0 | 04SEP2020 8:20 |
| | | 24SEP2020 21:00 | Malaise | Mild | 20 | 0 | 04SEP2020 8:20 |
| | | 25SEP2020 21:00 | Headache | Moderate | 21 | 1 | 04SEP2020 8:20 |
| | | 25SEP2020 21:00 | Fatigue | Moderate | 21 | 1 | 04SEP2020 8:20 |
| | | 25SEP2020 21:00 | Chills | Severe | 21 | 1 | 04SEP2020 8:20 |
| | | 25SEP2020 21:00 | Loss of Appetite | Moderate | 21 | 1 | 04SEP2020 8:20 |
| | | 25SEP2020 21:00 | Malaise | Moderate | 21 | 1 | 04SEP2020 8:20 |

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Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-------------|-----------------|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Older | 10272 | 25SEP2020 21:00 | Fever | Mild | 21 | 1 | 04SEP2020 8:20 |
| | 10303 | 07SEP2020 20:00 | Fatigue | Mild | 3 | | 04SEP2020 8:52 |
| | | 07SEP2020 20:00 | Myalgia | Mild | 3 | | 04SEP2020 8:52 |
| | | 08SEP2020 20:00 | Myalgia | Mild | 4 | | 04SEP2020 8:52 |
| | | 24SEP2020 20:00 | Fatigue | Mild | 20 | 0 | 04SEP2020 8:52 |
| | | 24SEP2020 20:00 | Chills | Mild | 20 | 0 | 04SEP2020 8:52 |
| | | 25SEP2020 20:00 | Nausea | Mild | 21 | 1 | 04SEP2020 8:52 |
| | | 25SEP2020 20:00 | Headache | Severe | 21 | 1 | 04SEP2020 8:52 |
| | | 25SEP2020 20:00 | Fatigue | Moderate | 21 | 1 | 04SEP2020 8:52 |
| | | 25SEP2020 20:00 | Myalgia | Moderate | 21 | 1 | 04SEP2020 8:52 |
| | | 25SEP2020 20:00 | Arthralgia | Mild | 21 | 1 | 04SEP2020 8:52 |
| | | 25SEP2020 20:00 | Chills | Moderate | 21 | 1 | 04SEP2020 8:52 |
| | | 25SEP2020 20:00 | Loss of Appetite | Mild | 21 | 1 | 04SEP2020 8:52 |
| | | 25SEP2020 20:00 | Malaise | Moderate | 21 | 1 | 04SEP2020 8:52 |
| | | 26SEP2020 20:00 | Diarrhea | Mild | 22 | 2 | 04SEP2020 8:52 |
| | | 26SEP2020 20:00 | Fatigue | Mild | 22 | 2 | 04SEP2020 8:52 |
| | 26SEP2020 20:00 | Loss of Appetite | Mild | 22 | 2 | 04SEP2020 8:52 | |
| 10305 | 05SEP2020 21:00 | Fatigue | Mild | 1 | | 04SEP2020 9:20 | |

Program: Lsaf_sysR_1.sas (Page 27 of 30)

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|-------------|--|-------------------------|-------------------|---------------------|---|---|---------------------------------|----------------|
| 30 µg Older | 10305 | 25SEP2020 21:00 | Fatigue | Mild | 21 | 0 | 04SEP2020 9:20 | |
| | | 26SEP2020 21:00 | Nausea | Mild | 22 | 1 | 04SEP2020 9:20 | |
| | | 26SEP2020 21:00 | Fatigue | Mild | 22 | 1 | 04SEP2020 9:20 | |
| | | 26SEP2020 21:00 | Myalgia | Mild | 22 | 1 | 04SEP2020 9:20 | |
| | | 26SEP2020 21:00 | Loss of Appetite | Mild | 22 | 1 | 04SEP2020 9:20 | |
| | | 26SEP2020 21:00 | Malaise | Mild | 22 | 1 | 04SEP2020 9:20 | |
| | | 26SEP2020 21:00 | Fever | Mild | 22 | 1 | 04SEP2020 9:20 | |
| | 10306 | 01SEP2020 20:00 | Headache | Moderate | 0 | | | 01SEP2020 9:20 |
| | | 01SEP2020 20:00 | Fatigue | Mild | 0 | | | 01SEP2020 9:20 |
| | | 01SEP2020 20:00 | Myalgia | Mild | 0 | | | 01SEP2020 9:20 |
| | | 22SEP2020 | Headache | Moderate | 21 | 0 | | 01SEP2020 9:20 |
| | | 22SEP2020 | Fatigue | Mild | 21 | 0 | | 01SEP2020 9:20 |
| | | 26SEP2020 20:00 | Headache | Mild | 25 | 4 | | 01SEP2020 9:20 |
| | 10308 | 25SEP2020 18:10 | Fatigue | Mild | 21 | 1 | | 04SEP2020 9:50 |
| | | 25SEP2020 18:10 | Arthralgia | Mild | 21 | 1 | | 04SEP2020 9:50 |
| | 10310 | 02SEP2020 20:00 | Fatigue | Mild | 0 | | | 02SEP2020 9:10 |
| | | 03SEP2020 20:00 | Headache | Mild | 1 | | | 02SEP2020 9:10 |
| | | 04SEP2020 20:00 | Headache | Mild | 2 | | | 02SEP2020 9:10 |
| | Program: Lsaf_sysR_1.sas (Page 28 of 30) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization | |
|-------------|--|-------------------------|-------------------|---------------------|---|---|---------------------------------|-----------------|
| 30 µg Older | 10310 | 23SEP2020 20:00 | Headache | Mild | 21 | 0 | 02SEP2020 9:10 | |
| | | 23SEP2020 20:00 | Myalgia | Mild | 21 | 0 | 02SEP2020 9:10 | |
| | | 23SEP2020 20:00 | Arthralgia | Mild | 21 | 0 | 02SEP2020 9:10 | |
| | | 23SEP2020 20:00 | Chills | Mild | 21 | 0 | 02SEP2020 9:10 | |
| | | 24SEP2020 20:00 | Headache | Moderate | 22 | 1 | 02SEP2020 9:10 | |
| | | 24SEP2020 20:00 | Chills | Mild | 22 | 1 | 02SEP2020 9:10 | |
| | | 24SEP2020 20:00 | Malaise | Mild | 22 | 1 | 02SEP2020 9:10 | |
| | 10314 | 02SEP2020 21:00 | Headache | Mild | 0 | | | 02SEP2020 9:40 |
| | | 23SEP2020 21:00 | Headache | Mild | 21 | 0 | | 02SEP2020 9:40 |
| | | 24SEP2020 21:00 | Malaise | Moderate | 22 | 1 | | 02SEP2020 9:40 |
| | 10316 | 01SEP2020 18:00 | Headache | Mild | 0 | | | 01SEP2020 8:30 |
| | | 01SEP2020 18:00 | Fatigue | Mild | 0 | | | 01SEP2020 8:30 |
| | | 01SEP2020 18:00 | Malaise | Mild | 0 | | | 01SEP2020 8:30 |
| | | 02SEP2020 0:00 | Fatigue | Mild | 1 | | | 01SEP2020 8:30 |
| | | 22SEP2020 | Headache | Mild | 21 | 0 | | 01SEP2020 8:30 |
| | | 22SEP2020 | Fatigue | Mild | 21 | 0 | | 01SEP2020 8:30 |
| | | 23SEP2020 23:30 | Headache | Mild | 22 | 1 | | 01SEP2020 8:30 |
| | 10319 | 06SEP2020 20:30 | Nausea | Mild | 2 | | | 04SEP2020 10:22 |
| | Program: Lsaf_sysR_1.sas (Page 29 of 30) | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

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Listing 16.2.3-1.3-3: Listing of solicited systemic reactions - BNT162b2

Safety set

| Dose group | Subject number | Date/time of collection | Systemic reaction | Severity/ Intensity | Number of days after prime immunization | Number of days after boost immunization | Date/time of prime immunization |
|-------------|--|-------------------------|-------------------|---------------------|---|---|---------------------------------|
| 30 µg Older | 10319 | 06SEP2020 20:30 | Diarrhea | Mild | 2 | | 04SEP2020 10:22 |
| | | 06SEP2020 20:30 | Fatigue | Mild | 2 | | 04SEP2020 10:22 |
| | | 06SEP2020 20:30 | Chills | Mild | 2 | | 04SEP2020 10:22 |
| | | 06SEP2020 20:30 | Malaise | Mild | 2 | | 04SEP2020 10:22 |
| | | 25SEP2020 20:30 | Myalgia | Mild | 21 | 1 | 04SEP2020 10:22 |
| | | 25SEP2020 20:30 | Chills | Moderate | 21 | 1 | 04SEP2020 10:22 |
| | | 25SEP2020 20:30 | Fever | Mild | 21 | 1 | 04SEP2020 10:22 |
| | 10323 | 25SEP2020 20:15 | Headache | Mild | 21 | 1 | 04SEP2020 10:50 |
| | | 25SEP2020 20:15 | Fatigue | Moderate | 21 | 1 | 04SEP2020 10:50 |
| | 10324 | 02SEP2020 20:10 | Headache | Mild | 0 | | 02SEP2020 10:10 |
| | | 08SEP2020 20:10 | Headache | Mild | 6 | | 02SEP2020 10:10 |
| | | 23SEP2020 20:30 | Headache | Mild | 21 | 0 | 02SEP2020 10:10 |
| | Program: Lsaf_sysR_1.sas (Page 30 of 30) | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 20153 1 µg Younger | fatigue Fatigue | 29JUN2020 16:00 | 30JUN2020 7:30 | 15.5 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | injection site reaction Injection site reaction | 29JUN2020 18:00 | 30JUN2020 18:00 | 24.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | sunburn between scapulae Sunburn | 09AUG2020 15:00 | 13AUG2020 8:00 | 89.0 21 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20154 1 µg Younger | dog bite (right thigh, approximately 2cm) Animal bite | 26JUL2020 20:00 | 07SEP2020 8:00 | 1020.0 7 | Not Applicable Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20158 1 µg Younger | gastroenteritis (abdominal discomfort, loose stool, CRP elevation) Abdominal discomfort | 18JUL2020 20:00 | 20JUL2020 16:00 | 44.0 6 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | gastroenteritis (abdominal discomfort, loose stool, CRP elevation) C-reactive protein increased | 18JUL2020 20:00 | 20JUL2020 16:00 | 44.0 6 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 1 of 33)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20158 1 µg Younger | gastroenteritis (abdominal discomfort, loosestool, CRP elevation) Diarrhoea | 18JUL2020 20:00 | 20JUL2020 16:00 | 44.0 6 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | gastroenteritis (abdominal discomfort, loosestool, CRP elevation) Gastroenteritis | 18JUL2020 20:00 | 20JUL2020 16:00 | 44.0 6 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | tonsillitis Tonsillitis | 10AUG2020 7:00 | 12AUG2020 17:00 | 58.0 8 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 20160 1 µg Younger | injection site reaction/pain Injection site reaction | 29JUN2020 20:00 | 29JUN2020 22:00 | 2.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Flu-like symptoms (headache, arthralgia, myalgia, malaise, fatigue) Influenza like illness | 29JUN2020 21:00 | 02JUL2020 9:00 | 60.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | flu-like symptoms (headache, malaise, fatigue) Influenza like illness | 03JUL2020 9:00 | 08JUL2020 8:00 | 119.0 5 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 2 of 33) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20163 1 µg Younger | fatigue Fatigue | 29JUN2020 10:05 | 29JUN2020 10:35 | 0.5 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20164 1 µg Younger | temporarily loss of smelling (for seconds), twice a day, every second day Sensory disturbance | 19AUG2020 14:00 | 22AUG2020 21:00 | 79.0 17 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20166 1 µg Younger | tiredness Fatigue | 29JUN2020 11:10 | 29JUN2020 23:00 | 11.8 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20188 1 µg Younger | sunburn upper body Sunburn | 16AUG2020 15:00 | 20AUG2020 8:00 | 89.0 20 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20189 1 µg Younger | flu-like symptoms Influenza like illness | 06SEP2020 6:00 | 07SEP2020 12:00 | 30.0 20 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 20176 3 µg Younger | swollen lymph node right site neck Lymphadenopathy | 29JUL2020 18:00 | 31JUL2020 21:00 | 51.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 3 of 33)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20192 3 µg Younger | abrasion right hand Skin abrasion | 10SEP2020 7:30 | 28SEP2020 16:00 | 440.5 24 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20194 3 µg Younger | tooth ache Toothache | 29JUL2020 18:00 | 30JUL2020 18:00 | 24.0 1 | Dose Not Changed Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | skin irritation (decoleté) (pimples, reddening) Skin irritation | 01AUG2020 13:00 | 04AUG2020 20:00 | 79.0 4 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | skin irritation perioral (after wearing mouth-nose-mask) Skin irritation | 19AUG2020 6:00 | 23AUG2020 22:00 | 112.0 2 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | tooth ache Toothache | 02OCT2020 12:00 | 07OCT2020 14:00 | 122.0 46 | Not Applicable Yes | Not Related Recovered/Resolved | Severe No | No No | No No |
| 20195 3 µg Younger | blepharitis Blepharitis | 11AUG2020 6:30 | 15AUG2020 6:30 | 96.0 12 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 4 of 33)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20195 3 µg Younger | abrasion right e bow Skin abrasion | 09SEP2020 10:00 | 16SEP2020 | - 22 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20197 3 µg Younger | Hematoma injection site Injection site haematoma | 29JUL2020 7:44 | 01AUG2020 8:00 | 72.3 2 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20201 3 µg Younger | hot flush Hot flush | 06AUG2020 12:15 | 06AUG2020 22:00 | 9.8 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | sore throat Oropharyngeal pain | 13AUG2020 16:00 | 13AUG2020 21:00 | 5.0 8 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | sore throat Oropharyngeal pain | 18AUG2020 14:00 | 19AUG2020 22:00 | 32.0 13 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | sore throat Oropharyngeal pain | 29AUG2020 13:00 | 29AUG2020 23:00 | 10.0 4 | Not Applicable Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 5 of 33) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|-----------------------------------|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 20201 3 µg Younger | sore throat Oropharyngeal pain | 30AUG2020 9:00 | 30AUG2020 23:00 | 14.0 5 | Not Applicable Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | sore throat Oropharyngeal pain | 01SEP2020 8:00 | 02SEP2020 23:00 | 39.0 7 | Not Applicable Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | headache Headache | 01SEP2020 10:00 | 03SEP2020 23:00 | 61.0 7 | Not Applicable Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | dysmenorrhea Dysmenorrhoea | 03SEP2020 10:30 | 06SEP2020 23:00 | 84.5 9 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | sorethroat Oropharyngeal pain | 05SEP2020 10:00 | 10SEP2020 20:00 | 130.0 11 | Not Applicable Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | tooth ache Toothache | 07SEP2020 19:30 | 09SEP2020 21:00 | 49.5 13 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 6 of 33)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 20201 3 µg Younger | dizziness Dizziness | 08SEP2020 10:00 | 10SEP2020 22:00 | 60.0 14 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | malaise Malaise | 11SEP2020 8:00 | 18SEP2020 8:00 | 168.0 17 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | suspicion of perianal thrombosis Haemorrhoids thrombosed | 11SEP2020 20:20 | 30SEP2020 20:00 | 455.7 17 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | fatigue Fatigue | 17SEP2020 8:00 | 18SEP2020 8:00 | 24.0 23 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 20203 3 µg Younger | wasp sting, pain, right lower arm Arthropod sting | 10AUG2020 6:00 | 14AUG2020 7:45 | 97.8 11 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | wasp sting, pain, right medial ankle Arthropod sting | 15AUG2020 21:30 | 24AUG2020 21:30 | 216.0 16 | Dose Not Changed Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 7 of 33)</p> | | | | | | | | | |

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20203 3 µg Younger | wasp sting, pain, left lower arm Arthropod sting | 17AUG2020 15:30 | 20AUG2020 6:45 | 63.3 18 | Dose Not Changed Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | common cold Nasopharyngitis | 01SEP2020 15:00 | 05SEP2020 10:00 | 91.0 12 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 20101 10 µg Younger | injection site reaction Injection site reaction | 17JUN2020 7:51 | 18JUN2020 22:00 | 38.2 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | flu-like symptoms Influenza like illness | 17JUN2020 12:00 | 18JUN2020 8:00 | 20.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | injection site reaction Injection site reaction | 07JUL2020 14:49 | 08JUL2020 21:00 | 30.2 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20102 10 µg Younger | injection site reaction Injection site reaction | 16JUN2020 8:46 | 18JUN2020 6:00 | 45.2 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 8 of 33)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20102 10 µg Younger | fatigue Fatigue | 16JUN2020 18:00 | 17JUN2020 6:00 | 12.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | injection site reaction Injection site reaction | 07JUL2020 13:51 | 08JUL2020 20:00 | 30.2 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | pain at venipuncture site Vessel puncture site pain | 07JUL2020 20:00 | 24JUL2020 20:00 | 408.0 1 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20103 10 µg Younger | fatigue Fatigue | 15JUN2020 20:10 | 16JUN2020 8:00 | 11.8 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | injection site reaction Injection site reaction | 16JUN2020 7:25 | 17JUN2020 20:17 | 36.9 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | headache Headache | 17JUN2020 12:00 | 17JUN2020 20:00 | 8.0 3 | Dose Not Changed Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 9 of 33)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20103 10 µg Younger | nausea Nausea | 20JUN2020 18:00 | 20JUN2020 19:00 | 1.0 6 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | injection site reaction Injection site reaction | 06JUL2020 16:30 | 09JUL2020 7:00 | 62.5 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | flu-like symptoms Influenza like illness | 06JUL2020 19:00 | 07JUL2020 7:00 | 12.0 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | pain left axilla Axillary pain | 08JUL2020 0:00 | 10JUL2020 18:00 | 66.0 3 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | sore throat Oropharyngeal pain | 11JUL2020 14:00 | 17JUL2020 8:00 | 138.0 6 | Not Applicable Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20104 10 µg Younger | injection site reaction Injection site reaction | 16JUN2020 12:50 | 19JUN2020 8:00 | 67.2 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 10 of 33)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20104 10 µg Younger | fatigue Fatigue | 17JUN2020 10:00 | 21JUN2020 9:00 | 95.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | headache Headache | 19JUN2020 19:43 | 20JUN2020 8:00 | 12.3 4 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | arthralgia(right hand) Arthralgia | 20JUN2020 8:00 | 21JUN2020 8:00 | 24.0 5 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | injection site reaction (pain, tenderness) Injection site reaction | 08JUL2020 6:30 | 09JUL2020 15:00 | 32.5 2 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | flu-like symptoms Influenza like illness | 08JUL2020 17:00 | 09JUL2020 0:30 | 7.5 2 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | fatigue Fatigue | 10JUL2020 10:00 | 10JUL2020 18:00 | 8.0 4 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 11 of 33)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20105 10 µg Younger | loose stools Diarrhoea | 16JUN2020 13:30 | 16JUN2020 18:00 | 4.5 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | injection site reaction Injection site reaction | 16JUN2020 16:47 | 17JUN2020 10:00 | 17.2 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | hematoma at venipuncture site Vessel puncture site haematoma | 16JUN2020 17:00 | 04JUL2020 8:00 | 423.0 1 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Headache Headache | 17JUN2020 13:00 | 17JUN2020 15:00 | 2.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | herpes pustula upperlip Oral herpes | 06JUL2020 16:00 | 10JUL2020 6:00 | 86.0 1 | Not Applicable Yes | Related Recovered/Resolved | Mild No | Yes No | No No |
| | flu-like symptoms (fever, shivering, myalgia, headache, diarrhea) Influenza like illness | 06JUL2020 19:30 | 08JUL2020 7:30 | 36.0 1 | Not Applicable Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 12 of 33)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-------------------------------|--|-----------------|---|
| 20105 10 µg Younger | injection site reaction (tenderness) Injection site reaction | 06JUL2020 20:02 | 08JUL2020 8:00 | 36.0 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | pain left axilla Axillary pain | 07JUL2020 7:30 | 09JUL2020 20:03 | 60.6 2 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20110 10 µg Younger | injection site reaction Injection site reaction | 16JUN2020 17:47 | 17JUN2020 17:00 | 23.2 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | arthralgia (knees) Arthralgia | 16JUN2020 19:00 | 16JUN2020 20:00 | 1.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Myalgia Myalgia | 16JUN2020 19:00 | 16JUN2020 20:00 | 1.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | injection site reaction Injection site reaction | 07JUL2020 13:30 | 08JUL2020 20:00 | 30.5 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 13 of 33)</p> | | | | | | | | | |

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 20110 10 µg Younger | flu-like symptoms (arthralgia, myalgia, headaches, fatigue) Influenza like illness | 08JUL2020 15:00 | 09JUL2020 20:00 | 29.0 2 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20111 10 µg Younger | flu-like symptoms (chills, increased temperature, fatigue) Influenza like illness | 18JUN2020 16:00 | 21JUN2020 8:00 | 64.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | injection site reaction Injection site reaction | 18JUN2020 16:56 | 21JUN2020 12:00 | 67.1 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | neck pain Neck pain | 03JUL2020 6:00 | 12JUL2020 20:00 | 230.0 16 | Dose Not Changed Yes | Not Related Recovered/Resolved | Severe No | Yes No | No No |
| | rhinitis Rhinitis | 08JUL2020 16:00 | 13JUL2020 8:00 | 112.0 21 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20114 10 µg Younger | flu-like symptoms (fatigue, increased temperature, headaches) Influenza like illness | 18JUN2020 15:30 | 19JUN2020 23:00 | 31.5 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 14 of 33) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 20114 10 µg Younger | injection site reaction Injection site reaction | 18JUN2020 16:00 | 20JUN2020 23:30 | 55.5 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | sunburn (shoulder,neck) Sunburn | 05JUL2020 13:00 | 08JUL2020 22:00 | 81.0 18 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Injection site reaction Injection site reaction | 09JUL2020 12:50 | 12JUL2020 5:30 | 64.7 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | sun-burn (back, forearm, leg) Sunburn | 31JUL2020 15:00 | 07AUG2020 7:00 | 160.0 23 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 20116 10 µg Younger | flu-like symptoms Influenza like illness | 18JUN2020 12:00 | 19JUN2020 21:00 | 33.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | injection site reaction Injection site reaction | 18JUN2020 15:02 | 20JUN2020 10:00 | 43.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 15 of 33) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 20116 10 µg Younger | inflammation left ear (upper auricle) External ear inflammation | 21JUN2020 14:00 | 28JUN2020 23:00 | 177.0 4 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | diarrhea Diarrhoea | 29JUN2020 10:00 | 30JUN2020 17:00 | 31.0 12 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | common cold Nasopharyngitis | 04JUL2020 18:00 | 22JUL2020 22:00 | 436.0 17 | Drug Withdrawn Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 20117 10 µg Younger | injection site reaction Injection site reaction | 18JUN2020 18:00 | 21JUN2020 9:00 | 63.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | headache Headache | 20JUN2020 10:00 | 20JUN2020 17:00 | 7.0 3 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | nausea Nausea | 20JUN2020 10:00 | 20JUN2020 17:00 | 7.0 3 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 16 of 33)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20117 10 µg Younger | injection site reaction Injection site reaction | 09JUL2020 16:45 | 10JUL2020 20:00 | 27.3 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20118 10 µg Younger | injection site reaction Injection site reaction | 18JUN2020 15:24 | 20JUN2020 8:00 | 40.6 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | fatigue Fatigue | 20JUN2020 8:00 | 21JUN2020 8:00 | 24.0 3 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | tooth pain after Tooth extraction Toothache | 29JUN2020 15:30 | 30JUN2020 6:00 | 14.5 12 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | injection site reaction Injection site reaction | 09JUL2020 17:41 | 13JUL2020 7:00 | 85.3 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20121 10 µg Younger | injection site reaction Injection site reaction | 18JUN2020 21:00 | 21JUN2020 22:00 | 73.0 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 17 of 33) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|---------------------------------------|--|-------------------------------|-------------------------------------|-----------------|--|
| 20121 10 µg Younger | injection site reaction Injection site reaction | 09JUL2020 14:13 | 11JUL2020 9:00 | 42.8 1 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 20156 20 µg Younger | injection site reaction Injection site reaction | 02JUL2020 18:00 | 03JUL2020 21:00 | 27.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | flu-like symptoms (fever, myalgia, fatigue, headache, arthralgia) Influenza like illness | 03JUL2020 12:00 | 03JUL2020 21:00 | 9.0 2 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 20159 20 µg Younger | injection site reaction (discomfort to touch) Injection site reaction | 01JUL2020 14:00 | 04JUL2020 8:00 | 66.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | fatigue Fatigue | 01JUL2020 17:00 | 03JUL2020 8:00 | 39.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | headache Headache | 02JUL2020 17:00 | 02JUL2020 20:00 | 3.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. | | | | | | | | | |
| Program: Lsaf_AE_1.sas (Page 18 of 33) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-------------------------------|--|-----------------|---|
| 20159 20 µg Younger | fatigue Fatigue | 04JUL2020 8:00 | 05JUL2020 8:00 | 24.0 4 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20168 20 µg Younger | headache Headache | 01JUL2020 11:30 | 01JUL2020 12:45 | 1.3 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | injection site reaction (discomfort to touch,pain) Injection site reaction | 01JUL2020 12:07 | 02JUL2020 21:00 | 32.9 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Fatigue Fatigue | 01JUL2020 16:00 | 01JUL2020 22:30 | 6.5 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | fatigue Fatigue | 03JUL2020 10:00 | 07JUL2020 22:00 | 108.0 3 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | headache Headache | 03JUL2020 10:00 | 07JUL2020 9:30 | 95.5 3 | Dose Not Changed Yes | Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 19 of 33)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20168 20 µg Younger | congested nose Nasal congestion | 23JUL2020 15:00 | 24JUL2020 7:00 | 16.0 2 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | sore throat Oropharyngeal pain | 23JUL2020 15:00 | 24JUL2020 7:00 | 16.0 2 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20172 20 µg Younger | injection site reaction Injection site reaction | 02JUL2020 12:18 | 04JUL2020 19:45 | 55.5 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | flu like symptoms Influenza like illness | 02JUL2020 18:00 | 03JUL2020 23:00 | 29.0 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | fatigue Fatigue | 06JUL2020 5:30 | 07JUL2020 8:00 | 26.5 5 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20173 20 µg Younger | injection site reaction (tenderness) Injection site reaction | 03JUL2020 6:30 | 03JUL2020 20:00 | 13.5 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 20 of 33)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 20174 20 µg Younger | injection site reaction (tenderness) Injection site reaction | 06JUL2020 17:33 | 09JUL2020 5:00 | 59.5 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 20175 20 µg Younger | injection site reaction(tenderness) Injection site reaction | 06JUL2020 15:35 | 08JUL2020 17:00 | 49.4 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | fatigue Fatigue | 06JUL2020 16:00 | 07JUL2020 8:00 | 16.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20177 20 µg Younger | injection site reaction Injection site reaction | 06JUL2020 18:00 | 08JUL2020 16:00 | 46.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | erythema at veinpuncture site from plaster (left cubital fossa) Vessel puncture site erythema | 07JUL2020 7:00 | 08JUL2020 8:00 | 25.0 2 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20178 20 µg Younger | fatigue Fatigue | 06JUL2020 17:00 | 07JUL2020 18:30 | 25.5 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 21 of 33) | | | | | | | | | |

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20178 20 µg Younger | injection site reaction Injection site reaction | 06JUL2020 22:00 | 07JUL2020 18:30 | 20.5 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20179 20 µg Younger | injection site reaction Injection site reaction | 06JUL2020 16:02 | 09JUL2020 20:45 | 76.7 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | fatigue Fatigue | 06JUL2020 19:00 | 08JUL2020 8:00 | 37.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20183 20 µg Younger | headache Headache | 23AUG2020 10:00 | 23AUG2020 12:00 | 2.0 21 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 20127 30 µg Younger | injection site reaction Injection site reaction | 22JUN2020 14:31 | 28JUN2020 8:30 | 138.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | fatigue Fatigue | 22JUN2020 19:00 | 28JUN2020 8:30 | 133.5 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. Program: Lsaf_AE_1.sas (Page 22 of 33) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 20134 30 µg Younger | injection site reaction Injection site reaction | 25JUN2020 13:30 | 26JUN2020 21:00 | 31.5 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20137 30 µg Younger | injection site reaction Injection site reaction | 23JUN2020 16:30 | 25JUN2020 20:30 | 52.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20138 30 µg Younger | injection site reaction Injection site reaction | 25JUN2020 16:30 | 27JUN2020 6:00 | 37.5 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | flu-like symptoms Influenza like illness | 25JUN2020 18:00 | 26JUN2020 17:00 | 23.0 1 | Dose Not Changed No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | stabbing pains in the heart region (probably stress induced) Non-cardiac chest pain | 26JUN2020 8:00 | 27JUN2020 6:00 | 22.0 2 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20142 30 µg Younger | flu-like symptoms (headache, nausea, shivering, fatigue) Influenza like illness | 26JUN2020 15:00 | 26JUN2020 22:00 | 7.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 23 of 33)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20142 30 µg Younger | tapeworm Cestode infection | 07JUL2020 6:50 | 08JUL2020 22:00 | 39.2 13 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20143 30 µg Younger | injection site reaction (tenderness) Injection site reaction | 25JUN2020 16:00 | 27JUN2020 22:00 | 54.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | flu-like symptoms (headache) Influenza like illness | 25JUN2020 20:00 | 25JUN2020 23:00 | 3.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20144 30 µg Younger | injection site reaction Injection site reaction | 25JUN2020 13:00 | 26JUN2020 7:00 | 18.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | headache Headache | 26JUN2020 5:00 | 26JUN2020 8:30 | 3.5 2 | Dose Not Changed Yes | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20145 30 µg Younger | injection site reaction Injection site reaction | 25JUN2020 14:00 | 27JUN2020 18:00 | 52.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 24 of 33)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20145 30 µg Younger | swelling at venipuncture site (right elbow) Vessel puncture site swelling | 25JUN2020 16:00 | 26JUN2020 8:00 | 16.0 1 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | flu like symptoms Influenza like illness | 25JUN2020 17:30 | 27JUN2020 18:00 | 48.5 1 | Dose Not Changed Yes | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20149 30 µg Younger | injection site reaction Injection site reaction | 22JUN2020 18:00 | 24JUN2020 8:35 | 38.6 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | muscle ache (after strenuous activity) Myalgia | 08JUL2020 7:00 | 09JUL2020 7:00 | 24.0 17 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20150 30 µg Younger | injection site reaction Injection site reaction | 23JUN2020 13:00 | 26JUN2020 16:05 | 75.1 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Diarrhea Diarrhoea | 27JUN2020 8:00 | 27JUN2020 14:06 | 6.1 5 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 25 of 33)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20150 30 µg Younger | sleeplessness Insomnia | 17JUL2020 0:00 | 18JUL2020 5:00 | 29.0 4 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | palpitation Palpitations | 17JUL2020 0:00 | 18JUL2020 5:00 | 29.0 4 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | hot flushes Hot flush | 17JUL2020 0:00 | 18JUL2020 5:00 | 29.0 4 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | sore throat Oropharyngeal pain | 18JUL2020 0:30 | 18JUL2020 5:00 | 4.5 5 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 20155 30 µg Younger | pain at venipuncture site (left elbow) Vessel puncture site pain | 23JUN2020 9:30 | 23JUN2020 20:30 | 11.0 1 | Dose Not Changed No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | numbness fingers (left hand) Hypoesthesia | 23JUN2020 14:00 | 24JUN2020 10:30 | 20.5 1 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 26 of 33)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 20155 30 µg Younger | injection site reaction Injection site reaction | 24JUN2020 0:00 | 24JUN2020 22:00 | 22.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | diarrhea Diarrhoea | 30JUN2020 7:00 | 30JUN2020 8:30 | 1.5 8 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 10267 10 µg Older | Dizziness Dizziness | 18AUG2020 10:00 | 18AUG2020 15:30 | 5.5 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Lumbalgia Back pain | 19AUG2020 7:00 | 19AUG2020 9:15 | 2.3 2 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Dizziness Dizziness | 19AUG2020 7:00 | 19AUG2020 11:00 | 4.0 2 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Dizziness Dizziness | 15SEP2020 9:00 | 17SEP2020 20:00 | 59.0 8 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 27 of 33)</p> | | | | | | | | | |

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10267 10 µg Older | Tiredness, malaise after blood drawing Fatigue | 15SEP2020 9:00 | 17SEP2020 20:00 | 59.0 8 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Tiredness, malaise after blood drawing Malaise | 15SEP2020 9:00 | 17SEP2020 20:00 | 59.0 8 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 10275 10 µg Older | Pain Achilles-Tender left Tendon pain | 21AUG2020 12:30 | 23AUG2020 8:00 | 43.5 2 | Dose Not Changed No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Flu like-symptoms (sweating, sore throat) Influenza like illness | 22AUG2020 7:00 | 22AUG2020 14:00 | 7.0 3 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Headache Headache | 26AUG2020 9:10 | 27AUG2020 7:00 | 21.8 7 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Heat flush face Hot flush | 10SEP2020 10:10 | 10SEP2020 15:00 | 4.8 1 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 28 of 33)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-------------------------------------|--|-----------------|---|
| 10300 10 µg Older | Tenderness injection site Injection site pain | 31AUG2020 7:00 | 08SEP2020 20:00 | 205.0 12 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Hematoma injection site Injection site haematoma | 01SEP2020 7:00 | 08SEP2020 20:00 | 181.0 13 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Seborrhoic eczema mouth, eyes, arms, knees Seborrhoic dermatitis | 04SEP2020 7:00 | 12SEP2020 8:00 | 193.0 16 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20214 20 µg Older | headache Headache | 10SEP2020 8:00 | 10SEP2020 16:00 | 8.0 16 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | toothache Toothache | 01OCT2020 7:00 | 09OCT2020 10:00 | 195.0 18 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 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 |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 29 of 33)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20223 20 µg Older | Amylase increased Amylase increased | 02SEP2020 7:28 | 07SEP2020 7:50 | 120.4 8 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Lipase increased Lipase increased | 02SEP2020 7:28 | 07SEP2020 7:50 | 120.4 8 | Dose Not Changed No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 20224 20 µg Older | muscle cramp right calf Muscle spasms | 03OCT2020 17:00 | 03OCT2020 18:00 | 1.0 12 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | headache Headache | 11OCT2020 9:00 | 11OCT2020 17:00 | 8.0 20 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | pain upper chest during deep inspiration (sore muscles) Painful respiration | 12OCT2020 9:00 | 13OCT2020 18:00 | 33.0 21 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | pain upper chest during deep inspiration (sore muscles) Painful respiration | 14OCT2020 8:00 | 14OCT2020 12:00 | 4.0 23 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 30 of 33)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 20225 20 µg Older | gastrointestinal complaints Gastrointestinal disorder | 09OCT2020 8:00 | 10OCT2020 8:00 | 24.0 26 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 20226 20 µg Older | injury under right eye medial from metall splinter Face injury | 08OCT2020 14:15 | 08OCT2020 14:30 | 0.3 17 | Not Applicable No | Not Related Recovered/Resolved | Severe No | Yes No | No No |
| 20233 20 µg Older | heartburn Dyspepsia | 06SEP2020 22:00 | 06SEP2020 23:00 | 1.0 6 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 10310 30 µg Older | Abdominal pain Abdominal pain | 11SEP2020 10:30 | 12SEP2020 0:00 | 13.5 10 | Dose Not Changed No | Not Related Recovered/Resolved | Severe No | Yes No | No No |
| | Lumbalgia Back pain | 11SEP2020 10:30 | 12SEP2020 0:00 | 13.5 10 | Dose Not Changed No | Not Related Recovered/Resolved | Severe No | Yes No | No No |
| | Headache Headache | 11SEP2020 10:30 | 12SEP2020 0:00 | 13.5 10 | Dose Not Changed No | Not Related Recovered/Resolved | Severe No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> | | | | | | | | | |
| <p>Program: Lsaf_AE_1.sas (Page 31 of 33)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 10316 30 µg Older | Headache Headache | 01OCT2020 10:30 | 02OCT2020 10:30 | 24.0 10 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10319 30 µg Older | Orthostatic dysregulation Orthostatic intolerance | 06SEP2020 7:10 | 06SEP2020 9:45 | 2.6 3 | Dose Not Changed No | Related Recovered/Resolved | Severe No | Yes No | No No |
| | Orthostatic dysregulation Orthostatic intolerance | 26SEP2020 7:00 | 26SEP2020 11:00 | 4.0 3 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10324 30 µg Older | Intermittent headache Headache | 31AUG2020 20:00 | 01SEP2020 22:00 | 26.0 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | No No | No No |
| | Mild pain left thorax and shoulder Chest pain | 02SEP2020 22:00 | 03SEP2020 12:30 | 14.5 1 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Mild pain left thorax and shoulder Musculoskeletal pain | 02SEP2020 22:00 | 03SEP2020 12:30 | 14.5 1 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_1.sas (Page 32 of 33)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.5-3: Listing of 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|------------------------------|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 10324 30 µg Older | Renal colic Renal colic | 03SEP2020 15:30 | 04SEP2020 4:45 | 13.3 2 | Dose Not Changed No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Headache Headache | 30SEP2020 14:15 | 30SEP2020 22:30 | 8.3 8 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | Headache Headache | 12OCT2020 7:00 | 12OCT2020 23:40 | 16.7 20 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> | | | | | | | | | |
| <p>Program: Lsaf_AE_1.sas (Page 33 of 33)</p> | | | | | | | | | |

Listing 16.2.3-1.6-3: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20153 1 µg Younger | sunburn between scapulae Sunburn | 09AUG2020 15:00 | 13AUG2020 8:00 | 89.0 21 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20154 1 µg Younger | dog bite (right thigh, approximately 2cm) Animal bite | 26JUL2020 20:00 | 07SEP2020 8:00 | 1020.0 7 | Not Applicable Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20158 1 µg Younger | gastroenteritis (abdominal discomfort, loosestool, CRP elevation) Abdominal discomfort | 18JUL2020 20:00 | 20JUL2020 16:00 | 44.0 6 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | gastroenteritis (abdominal discomfort, loosestool, CRP elevation) Gastroenteritis | 18JUL2020 20:00 | 20JUL2020 16:00 | 44.0 6 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | tonsillitis Tonsillitis | 10AUG2020 7:00 | 12AUG2020 17:00 | 58.0 8 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 20164 1 µg Younger | temporarily loss of smelling (for seconds), twice a day, every second day Sensory disturbance | 19AUG2020 14:00 | 22AUG2020 21:00 | 79.0 17 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 1 of 12)</p> | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.6-3: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 20188 1 µg Younger | sunburn upper body Sunburn | 16AUG2020 15:00 | 20AUG2020 8:00 | 89.0 20 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20176 3 µg Younger | swollen lymph node right site neck Lymphadenopathy | 29JUL2020 18:00 | 31JUL2020 21:00 | 51.0 1 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20192 3 µg Younger | abrasion right hand Skin abrasion | 10SEP2020 7:30 | 28SEP2020 16:00 | 440.5 24 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20194 3 µg Younger | tooth ache Toothache | 29JUL2020 18:00 | 30JUL2020 18:00 | 24.0 1 | Dose Not Changed Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | skin irritation (decoleté) (pimples, reddening) Skin irritation | 01AUG2020 13:00 | 04AUG2020 20:00 | 79.0 4 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | skin irritation perioral (after wearing mouth-nose-mask) Skin irritation | 19AUG2020 6:00 | 23AUG2020 22:00 | 112.0 2 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. | | | | | | | | | |
| Program: Lsaf_AE_2.sas (Page 2 of 12) | | | | | | | | | |

Staburo GmbH. Based on clean SDTM data received on 03NOV2020. Data cut-off: 23OCT2020.

Listing 16.2.3-1.6-3: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20194 3 µg Younger | tooth ache Toothache | 02OCT2020 12:00 | 07OCT2020 14:00 | 122.0 46 | Not Applicable Yes | Not Related Recovered/Resolved | Severe No | No No | No No |
| 20195 3 µg Younger | blepharitis Blepharitis | 11AUG2020 6:30 | 15AUG2020 6:30 | 96.0 12 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | abrasion right e bow Skin abrasion | 09SEP2020 10:00 | 16SEP2020 | - 22 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20197 3 µg Younger | Hematoma injection site Injection site haematoma | 29JUL2020 7:44 | 01AUG2020 8:00 | 72.3 2 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20201 3 µg Younger | sore throat Oropharyngeal pain | 13AUG2020 16:00 | 13AUG2020 21:00 | 5.0 8 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | sore throat Oropharyngeal pain | 18AUG2020 14:00 | 19AUG2020 22:00 | 32.0 13 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available. | | | | | | | | | |
| Program: Lsaf_AE_2.sas (Page 3 of 12) | | | | | | | | | |

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Listing 16.2.3-1.6-3: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|-----------------------------------|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20201 3 µg Younger | sore throat Oropharyngeal pain | 29AUG2020 13:00 | 29AUG2020 23:00 | 10.0 4 | Not Applicable Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | sore throat Oropharyngeal pain | 30AUG2020 9:00 | 30AUG2020 23:00 | 14.0 5 | Not Applicable Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | sore throat Oropharyngeal pain | 01SEP2020 8:00 | 02SEP2020 23:00 | 39.0 7 | Not Applicable Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | dysmenorrhea Dysmenorrhoea | 03SEP2020 10:30 | 06SEP2020 23:00 | 84.5 9 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | sorethroat Oropharyngeal pain | 05SEP2020 10:00 | 10SEP2020 20:00 | 130.0 11 | Not Applicable Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | tooth ache Toothache | 07SEP2020 19:30 | 09SEP2020 21:00 | 49.5 13 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 4 of 12)</p> | | | | | | | | | |

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Listing 16.2.3-1.6-3: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 20201 3 µg Younger | malaise Malaise | 11SEP2020 8:00 | 18SEP2020 8:00 | 168.0 17 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | suspicion of perianal thrombosis Haemorrhoids thrombosed | 11SEP2020 20:20 | 30SEP2020 20:00 | 455.7 17 | Not Applicable Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 20203 3 µg Younger | wasp sting, pain, right lower arm Arthropod sting | 10AUG2020 6:00 | 14AUG2020 7:45 | 97.8 11 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | wasp sting, pain, right medial ankle Arthropod sting | 15AUG2020 21:30 | 24AUG2020 21:30 | 216.0 16 | Dose Not Changed Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | wasp sting, pain, left lower arm Arthropod sting | 17AUG2020 15:30 | 20AUG2020 6:45 | 63.3 18 | Dose Not Changed Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | common cold Nasopharyngitis | 01SEP2020 15:00 | 05SEP2020 10:00 | 91.0 12 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 5 of 12)</p> | | | | | | | | | |

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Listing 16.2.3-1.6-3: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20102 10 µg Younger | pain at venipuncture site Vessel puncture site pain | 07JUL2020 20:00 | 24JUL2020 20:00 | 408.0 1 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20103 10 µg Younger | sore throat Oropharyngeal pain | 11JUL2020 14:00 | 17JUL2020 8:00 | 138.0 6 | Not Applicable Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20105 10 µg Younger | hematoma at venipuncture site Vessel puncture site haematoma | 16JUN2020 17:00 | 04JUL2020 8:00 | 423.0 1 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | herpes pustula upperlip Oral herpes | 06JUL2020 16:00 | 10JUL2020 6:00 | 86.0 1 | Not Applicable Yes | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20111 10 µg Younger | neck pain Neck pain | 03JUL2020 6:00 | 12JUL2020 20:00 | 230.0 16 | Dose Not Changed Yes | Not Related Recovered/Resolved | Severe No | Yes No | No No |
| | rhinitis Rhinitis | 08JUL2020 16:00 | 13JUL2020 8:00 | 112.0 21 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 6 of 12)</p> | | | | | | | | | |

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Listing 16.2.3-1.6-3: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20114 10 µg Younger | sunburn (shoulder,neck) Sunburn | 05JUL2020 13:00 | 08JUL2020 22:00 | 81.0 18 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | sun-burn (back, forearm, leg) Sunburn | 31JUL2020 15:00 | 07AUG2020 7:00 | 160.0 23 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 20116 10 µg Younger | inflammation left ear (upper auricle) External ear inflammation | 21JUN2020 14:00 | 28JUN2020 23:00 | 177.0 4 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | common cold Nasopharyngitis | 04JUL2020 18:00 | 22JUL2020 22:00 | 436.0 17 | Drug Withdrawn Yes | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 20118 10 µg Younger | tooth pain after Tooth extraction Toothache | 29JUN2020 15:30 | 30JUN2020 6:00 | 14.5 12 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20168 20 µg Younger | congested nose Nasal congestion | 23JUL2020 15:00 | 24JUL2020 7:00 | 16.0 2 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 7 of 12)</p> | | | | | | | | | |

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Listing 16.2.3-1.6-3: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|--|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20168 20 µg Younger | sore throat Oropharyngeal pain | 23JUL2020 15:00 | 24JUL2020 7:00 | 16.0 2 | Not Applicable No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20177 20 µg Younger | erythema at veinpuncture site from plaster (left cubital fossa) Vessel puncture site erythema | 07JUL2020 7:00 | 08JUL2020 8:00 | 25.0 2 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20138 30 µg Younger | stabbing pains in the heart region (probably stress induced) Non-cardiac chest pain | 26JUN2020 8:00 | 27JUN2020 6:00 | 22.0 2 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20142 30 µg Younger | tapeworm Cestode infection | 07JUL2020 6:50 | 08JUL2020 22:00 | 39.2 13 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20145 30 µg Younger | swelling at venipuncture site (right elbow) Vessel puncture site swelling | 25JUN2020 16:00 | 26JUN2020 8:00 | 16.0 1 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20150 30 µg Younger | sleeplessness Insomnia | 17JUL2020 0:00 | 18JUL2020 5:00 | 29.0 4 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 8 of 12)</p> | | | | | | | | | |

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Listing 16.2.3-1.6-3: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|--|---|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 20150 30 µg Younger | palpitation Palpitations | 17JUL2020 0:00 | 18JUL2020 5:00 | 29.0 4 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| | sore throat Oropharyngeal pain | 18JUL2020 0:30 | 18JUL2020 5:00 | 4.5 5 | Not Applicable No | Related Recovered/Resolved | Moderate No | Yes No | No No |
| 20155 30 µg Younger | pain at venipuncture site (left elbow) Vessel puncture site pain | 23JUN2020 9:30 | 23JUN2020 20:30 | 11.0 1 | Dose Not Changed No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | numbness fingers (left hand) Hypoesthesia | 23JUN2020 14:00 | 24JUN2020 10:30 | 20.5 1 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 10267 10 µg Older | Lumbalgia Back pain | 19AUG2020 7:00 | 19AUG2020 9:15 | 2.3 2 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 10275 10 µg Older | Pain Achilles-Tender left Tendon pain | 21AUG2020 12:30 | 23AUG2020 8:00 | 43.5 2 | Dose Not Changed No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 9 of 12)</p> | | | | | | | | | |

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Listing 16.2.3-1.6-3: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|--|--|-------------------------------------|--|-----------------|---|
| 10300 10 µg Older | Tenderness injection site Injection site pain | 31AUG2020 7:00 | 08SEP2020 20:00 | 205.0 12 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Hematoma injection site Injection site haematoma | 01SEP2020 7:00 | 08SEP2020 20:00 | 181.0 13 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| | Seborrheic eczema mouth, eyes, arms, knees Seborrheic dermatitis | 04SEP2020 7:00 | 12SEP2020 8:00 | 193.0 16 | Dose Not Changed No | Related Recovered/Resolved | Mild No | Yes No | No No |
| 20214 20 µg Older | toothache Toothache | 01OCT2020 7:00 | 09OCT2020 10:00 | 195.0 18 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 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 |
| 20223 20 µg Older | Amylase increased Amylase increased | 02SEP2020 7:28 | 07SEP2020 7:50 | 120.4 8 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 10 of 12)</p> | | | | | | | | | |

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Listing 16.2.3-1.6-3: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Serious- ness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|---|---------------------|--------------------|--|--|-----------------------------------|--|-----------------|---|
| 20223 20 µg Older | Lipase increased Lipase increased | 02SEP2020 7:28 | 07SEP2020 7:50 | 120.4 8 | Dose Not Changed No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 20224 20 µg Older | muscle cramp right calf Muscle spasms | 03OCT2020 17:00 | 03OCT2020 18:00 | 1.0 12 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| | pain upper chest during deep inspiration (sore muscles) Painful respiration | 12OCT2020 9:00 | 13OCT2020 18:00 | 33.0 21 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | pain upper chest during deep inspiration (sore muscles) Painful respiration | 14OCT2020 8:00 | 14OCT2020 12:00 | 4.0 23 | Not Applicable No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| 20226 20 µg Older | injury under right eye medial from metall splinter Face injury | 08OCT2020 14:15 | 08OCT2020 14:30 | 0.3 17 | Not Applicable No | Not Related Recovered/Resolved | Severe No | Yes No | No No |
| 20233 20 µg Older | heartburn Dyspepsia | 06SEP2020 22:00 | 06SEP2020 23:00 | 1.0 6 | Dose Not Changed Yes | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 11 of 12)</p> | | | | | | | | | |

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Listing 16.2.3-1.6-3: Listing of adverse events without adverse events based on solicited reporting via diaries - 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 ¹ / Seriousness | TEAE/ TEAESI | Epi-/pandemic related indicator/ Dose limiting toxicity |
|---|--|---------------------|--------------------|---------------------------------------|--|-----------------------------------|-------------------------------------|-----------------|--|
| 10310 30 µg Older | Lumbalgia Back pain | 11SEP2020 10:30 | 12SEP2020 0:00 | 13.5 10 | Dose Not Changed No | Not Related Recovered/Resolved | Severe No | Yes No | No No |
| 10319 30 µg Older | Orthostatic dysregulation Orthostatic intolerance | 06SEP2020 7:10 | 06SEP2020 9:45 | 2.6 3 | Dose Not Changed No | Related Recovered/Resolved | Severe No | Yes No | No No |
| | Orthostatic dysregulation Orthostatic intolerance | 26SEP2020 7:00 | 26SEP2020 11:00 | 4.0 3 | Not Applicable No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| 10324 30 µg Older | Mild pain left thorax and shoulder Chest pain | 02SEP2020 22:00 | 03SEP2020 12:30 | 14.5 1 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Mild pain left thorax and shoulder Musculoskeletal pain | 02SEP2020 22:00 | 03SEP2020 12:30 | 14.5 1 | Dose Not Changed No | Not Related Recovered/Resolved | Mild No | Yes No | No No |
| | Renal colic Renal colic | 03SEP2020 15:30 | 04SEP2020 4:45 | 13.3 2 | Dose Not Changed No | Not Related Recovered/Resolved | Moderate No | Yes No | No No |
| <p>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. TEAE = Treatment emergent adverse event; TEAESI = TEAE of special interest; - = not available.</p> <p>Program: Lsaf_AE_2.sas (Page 12 of 12)</p> | | | | | | | | | |

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