

Table 14.1.1.1.1.1
Subject Disposition by Baseline SARS-CoV-2 Status
Randomization Set

| | Baseline SARS-CoV-2 Negative | | | Baseline SARS-CoV-2 Positive | | | Overall | | |
|--|------------------------------|------------------------|--------------------|------------------------------|----------------------|------------------|----------------------|------------------------|--------------------|
| | Placebo (N=14370) | mRNA-1273 (N=14312) | Total (N=28682) | Placebo (N=334) | mRNA-1273 (N=341) | Total (N=675) | Placebo (N=15210) | mRNA-1273 (N=15208) | Total (N=30418) |
| | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| Number of Subjects | | | | | | | | | |
| Received First Injection | 14370 (100) | 14312 (100) | 28682 (100) | 334 (100) | 341 (100) | 675 (100) | 15170 (99.7) | 15180 (99.8) | 30350 (99.8) |
| Received Second Injection | 13291 (92.5) | 13316 (93.0) | 26607 (92.8) | 215 (64.4) | 205 (60.1) | 420 (62.2) | 13916 (91.5) | 13982 (91.9) | 27898 (91.7) |
| Discontinued Study Vaccine | 198 (1.4) | 132 (0.9) | 330 (1.2) | 38 (11.4) | 43 (12.6) | 81 (12.0) | 254 (1.7) | 188 (1.2) | 442 (1.5) |
| Reason for Discontinuation of Study Vaccine | | | | | | | | | |
| Adverse Event | 25 (0.2) | 18 (0.1) | 43 (0.1) | 2 (0.6) | 4 (1.2) | 6 (0.9) | 28 (0.2) | 24 (0.2) | 52 (0.2) |
| Serious Adverse Event | 12 (<0.1) | 4 (<0.1) | 16 (<0.1) | 2 (0.6) | 0 | 2 (0.3) | 14 (<0.1) | 5 (<0.1) | 19 (<0.1) |
| Death | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) | 0 | 0 | 0 | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Lost to Follow-Up | 19 (0.1) | 14 (<0.1) | 33 (0.1) | 1 (0.3) | 3 (0.9) | 4 (0.6) | 20 (0.1) | 18 (0.1) | 38 (0.1) |
| Physician Decision | 8 (<0.1) | 14 (<0.1) | 22 (<0.1) | 0 | 0 | 0 | 10 (<0.1) | 15 (<0.1) | 25 (<0.1) |
| Pregnancy | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) | 0 | 0 | 0 | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Protocol Deviation | 4 (<0.1) | 2 (<0.1) | 6 (<0.1) | 0 | 0 | 0 | 4 (<0.1) | 2 (<0.1) | 6 (<0.1) |

Percentages are based on the number of randomized subjects.

[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.1.1.1.1
Subject Disposition by Baseline SARS-CoV-2 Status
Randomization Set

| | Baseline SARS-CoV-2 Negative | | | Baseline SARS-CoV-2 Positive | | | Overall | | |
|--|------------------------------|------------------------|--------------------|------------------------------|----------------------|------------------|----------------------|------------------------|--------------------|
| | Placebo (N=14370) | mRNA-1273 (N=14312) | Total (N=28682) | Placebo (N=334) | mRNA-1273 (N=341) | Total (N=675) | Placebo (N=15210) | mRNA-1273 (N=15208) | Total (N=30418) |
| | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| Reason for Discontinuation of Study Vaccine (Cont.) | | | | | | | | | |
| Study Terminated by Sponsor | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Withdrawal of Consent by Participant | 75 (0.5) | 45 (0.3) | 120 (0.4) | 5 (1.5) | 1 (0.3) | 6 (0.9) | 91 (0.6) | 48 (0.3) | 139 (0.5) |
| Due to SARS-CoV-2 | 25 (0.2) | 4 (<0.1) | 29 (0.1) | 24 (7.2) | 29 (8.5) | 53 (7.9) | 49 (0.3) | 35 (0.2) | 84 (0.3) |
| Other | 26 (0.2) | 26 (0.2) | 52 (0.2) | 4 (1.2) | 6 (1.8) | 10 (1.5) | 34 (0.2) | 36 (0.2) | 70 (0.2) |
| Completed Study [1] | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Discontinued from Study | 139 (1.0) | 105 (0.7) | 244 (0.9) | 8 (2.4) | 4 (1.2) | 12 (1.8) | 168 (1.1) | 120 (0.8) | 288 (0.9) |
| Reason for Discontinuation of Study | | | | | | | | | |
| Adverse Event | 0 | 1 (<0.1) | 1 (<0.1) | 0 | 0 | 0 | 0 | 2 (<0.1) | 2 (<0.1) |
| Serious Adverse Event | 0 | 1 (<0.1) | 1 (<0.1) | 0 | 0 | 0 | 0 | 1 (<0.1) | 1 (<0.1) |

Percentages are based on the number of randomized subjects.

[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.1.1.1.1
Subject Disposition by Baseline SARS-CoV-2 Status
Randomization Set

| | Baseline SARS-CoV-2 Negative | | | Baseline SARS-CoV-2 Positive | | | Overall | | |
|--|------------------------------|------------------------|--------------------|------------------------------|----------------------|------------------|----------------------|------------------------|--------------------|
| | Placebo (N=14370) | mRNA-1273 (N=14312) | Total (N=28682) | Placebo (N=334) | mRNA-1273 (N=341) | Total (N=675) | Placebo (N=15210) | mRNA-1273 (N=15208) | Total (N=30418) |
| | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| Reason for Discontinuation of Study (Cont.) | | | | | | | | | |
| Death | 4 (<0.1) | 3 (<0.1) | 7 (<0.1) | 0 | 0 | 0 | 4 (<0.1) | 3 (<0.1) | 7 (<0.1) |
| Lost to Follow-Up | 29 (0.2) | 16 (0.1) | 45 (0.2) | 2 (0.6) | 3 (0.9) | 5 (0.7) | 31 (0.2) | 20 (0.1) | 51 (0.2) |
| Physician Decision | 1 (<0.1) | 15 (0.1) | 16 (<0.1) | 0 | 0 | 0 | 2 (<0.1) | 17 (0.1) | 19 (<0.1) |
| Pregnancy | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Protocol Deviation | 0 | 1 (<0.1) | 1 (<0.1) | 0 | 0 | 0 | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Study Terminated by Sponsor | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Withdrawal of Consent by Participant | 101 (0.7) | 63 (0.4) | 164 (0.6) | 6 (1.8) | 1 (0.3) | 7 (1.0) | 120 (0.8) | 67 (0.4) | 187 (0.6) |
| Other | 4 (<0.1) | 5 (<0.1) | 9 (<0.1) | 0 | 0 | 0 | 10 (<0.1) | 9 (<0.1) | 19 (<0.1) |

Percentages are based on the number of randomized subjects.

[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.1.1.1.2
Subject Disposition by Age Group
Randomization Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|--|--------------------|-----------------|-----------------|----------------|-----------------|----------------|-----------------|-----------------|-----------------|
| | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total |
| | (N=11448) | (N=11437) | (N=22885) | (N=3762) | (N=3771) | (N=7533) | (N=15210) | (N=15208) | (N=30418) |
| | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| Number of Subjects | | | | | | | | | |
| Received First Injection | 11418 (99.7) | 11412 (99.8) | 22830 (99.8) | 3752 (99.7) | 3768 (>99.9) | 7520 (99.8) | 15170 (99.7) | 15180 (99.8) | 30350 (99.8) |
| Received Second Injection | 10348 (90.4) | 10382 (90.8) | 20730 (90.6) | 3568 (94.8) | 3600 (95.5) | 7168 (95.2) | 13916 (91.5) | 13982 (91.9) | 27898 (91.7) |
| Discontinued Study Vaccine | 210 (1.8) | 161 (1.4) | 371 (1.6) | 44 (1.2) | 27 (0.7) | 71 (0.9) | 254 (1.7) | 188 (1.2) | 442 (1.5) |
| Reason for Discontinuation of Study Vaccine | | | | | | | | | |
| Adverse Event | 24 (0.2) | 19 (0.2) | 43 (0.2) | 4 (0.1) | 5 (0.1) | 9 (0.1) | 28 (0.2) | 24 (0.2) | 52 (0.2) |
| Serious Adverse Event | 6 (<0.1) | 3 (<0.1) | 9 (<0.1) | 8 (0.2) | 2 (<0.1) | 10 (0.1) | 14 (<0.1) | 5 (<0.1) | 19 (<0.1) |
| Death | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Lost to Follow-Up | 20 (0.2) | 18 (0.2) | 38 (0.2) | 0 (0.2) | 0 (<0.1) | 0 (<0.1) | 20 (0.1) | 18 (0.1) | 38 (0.1) |
| Physician Decision | 9 (<0.1) | 13 (0.1) | 22 (<0.1) | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) | 10 (<0.1) | 15 (<0.1) | 25 (<0.1) |
| Pregnancy | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) | 0 (<0.1) | 0 (<0.1) | 0 (<0.1) | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Protocol Deviation | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) | 1 (<0.1) | 0 (<0.1) | 1 (<0.1) | 4 (<0.1) | 2 (<0.1) | 6 (<0.1) |

Percentages are based on the number of randomized subjects.

[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.1.1.1.2
Subject Disposition by Age Group
Randomization Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|---|--------------------|-----------|-----------|------------|-----------|----------|-----------|-----------|-----------|
| | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total |
| | (N=11448) | (N=11437) | (N=22885) | (N=3762) | (N=3771) | (N=7533) | (N=15210) | (N=15208) | (N=30418) |
| | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| Reason for Discontinuation of Study Vaccine (Cont.) | | | | | | | | | |
| Study Terminated by Sponsor | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Withdrawal of Consent by Participant | 72 (0.6) | 38 (0.3) | 110 (0.5) | 19 (0.5) | 10 (0.3) | 29 (0.4) | 91 (0.6) | 48 (0.3) | 139 (0.5) |
| Due to SARS-CoV-2 | 45 (0.4) | 31 (0.3) | 76 (0.3) | 4 (0.1) | 4 (0.1) | 8 (0.1) | 49 (0.3) | 35 (0.2) | 84 (0.3) |
| Other | 28 (0.2) | 33 (0.3) | 61 (0.3) | 6 (0.2) | 3 (<0.1) | 9 (0.1) | 34 (0.2) | 36 (0.2) | 70 (0.2) |
| Completed Study [1] | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Discontinued from Study | 134 (1.2) | 104 (0.9) | 238 (1.0) | 34 (0.9) | 16 (0.4) | 50 (0.7) | 168 (1.1) | 120 (0.8) | 288 (0.9) |
| Reason for Discontinuation of Study | | | | | | | | | |
| Adverse Event | 0 | 1 (<0.1) | 1 (<0.1) | 0 | 1 (<0.1) | 1 (<0.1) | 0 | 2 (<0.1) | 2 (<0.1) |
| Serious Adverse Event | 0 | 0 | 0 | 0 | 1 (<0.1) | 1 (<0.1) | 0 | 1 (<0.1) | 1 (<0.1) |

Percentages are based on the number of randomized subjects.

[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.1.1.1.2
Subject Disposition by Age Group
Randomization Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|--|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=11448) | mRNA-1273 (N=11437) | Total (N=22885) | Placebo (N=3762) | mRNA-1273 (N=3771) | Total (N=7533) | Placebo (N=15210) | mRNA-1273 (N=15208) | Total (N=30418) |
| | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| Reason for Discontinuation of Study (Cont.) | | | | | | | | | |
| Death | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) | 4 (<0.1) | 3 (<0.1) | 7 (<0.1) |
| Lost to Follow-Up | 31 (0.3) | 20 (0.2) | 51 (0.2) | 0 | 0 | 0 | 31 (0.2) | 20 (0.1) | 51 (0.2) |
| Physician Decision | 1 (<0.1) | 16 (0.1) | 17 (<0.1) | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) | 2 (<0.1) | 17 (0.1) | 19 (<0.1) |
| Pregnancy | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Protocol Deviation | 0 | 1 (<0.1) | 1 (<0.1) | 1 (<0.1) | 0 | 1 (<0.1) | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Study Terminated by Sponsor | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Withdrawal of Consent by Participant | 95 (0.8) | 56 (0.5) | 151 (0.7) | 25 (0.7) | 11 (0.3) | 36 (0.5) | 120 (0.8) | 67 (0.4) | 187 (0.6) |
| Other | 6 (<0.1) | 8 (<0.1) | 14 (<0.1) | 4 (0.1) | 1 (<0.1) | 5 (<0.1) | 10 (<0.1) | 9 (<0.1) | 19 (<0.1) |

Percentages are based on the number of randomized subjects.

[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

Randomization Stratum: Overall

| | Placebo (N=15210) n (%) | mRNA-1273 (N=15208) n (%) | Total (N=30418) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Number of Subjects | | | |
| Received First Injection | 15170 (99.7) | 15180 (99.8) | 30350 (99.8) |
| Received Second Injection | 13916 (91.5) | 13982 (91.9) | 27898 (91.7) |
| Discontinued Study Vaccine | 254 (1.7) | 188 (1.2) | 442 (1.5) |
| Reason for Discontinuation of Study Vaccine | | | |
| Adverse Event | 28 (0.2) | 24 (0.2) | 52 (0.2) |
| Serious Adverse Event | 14 (<0.1) | 5 (<0.1) | 19 (<0.1) |
| Death | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Lost to Follow-Up | 20 (0.1) | 18 (0.1) | 38 (0.1) |
| Physician Decision | 10 (<0.1) | 15 (<0.1) | 25 (<0.1) |
| Pregnancy | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Protocol Deviation | 4 (<0.1) | 2 (<0.1) | 6 (<0.1) |
| Study Terminated by Sponsor | 0 | 0 | 0 |
| Withdrawal of Consent by Participant | 91 (0.6) | 48 (0.3) | 139 (0.5) |
| Due to SARS-CoV-2 | 49 (0.3) | 35 (0.2) | 84 (0.3) |
| Other | 34 (0.2) | 36 (0.2) | 70 (0.2) |

Percentages are based on the number of randomized subjects.

[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

Randomization Stratum: Overall

| | Placebo (N=15210) n (%) | mRNA-1273 (N=15208) n (%) | Total (N=30418) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Completed Study [1] | 0 | 0 | 0 |
| Discontinued from Study | 168 (1.1) | 120 (0.8) | 288 (0.9) |
| Reason for Discontinuation of Study | | | |
| Adverse Event | 0 | 2 (<0.1) | 2 (<0.1) |
| Serious Adverse Event | 0 | 1 (<0.1) | 1 (<0.1) |
| Death | 4 (<0.1) | 3 (<0.1) | 7 (<0.1) |
| Lost to Follow-Up | 31 (0.2) | 20 (0.1) | 51 (0.2) |
| Physician Decision | 2 (<0.1) | 17 (0.1) | 19 (<0.1) |
| Pregnancy | 0 | 0 | 0 |
| Protocol Deviation | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Study Terminated by Sponsor | 0 | 0 | 0 |
| Withdrawal of Consent by Participant | 120 (0.8) | 67 (0.4) | 187 (0.6) |
| Other | 10 (<0.1) | 9 (<0.1) | 19 (<0.1) |

Percentages are based on the number of randomized subjects.

[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

| | Placebo (N=8910) n (%) | mRNA-1273 (N=8908) n (%) | Total (N=17818) n (%) |
|---|------------------------------|--------------------------------|-----------------------------|
| Number of Subjects | | | |
| Received First Injection | 8886 (99.7) | 8887 (99.8) | 17773 (99.7) |
| Received Second Injection | 8028 (90.1) | 8029 (90.1) | 16057 (90.1) |
| Discontinued Study Vaccine | 165 (1.9) | 137 (1.5) | 302 (1.7) |
| Reason for Discontinuation of Study Vaccine | | | |
| Adverse Event | 21 (0.2) | 16 (0.2) | 37 (0.2) |
| Serious Adverse Event | 5 (<0.1) | 2 (<0.1) | 7 (<0.1) |
| Death | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Lost to Follow-Up | 19 (0.2) | 16 (0.2) | 35 (0.2) |
| Physician Decision | 7 (<0.1) | 10 (0.1) | 17 (<0.1) |
| Pregnancy | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Protocol Deviation | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Study Terminated by Sponsor | 0 | 0 | 0 |
| Withdrawal of Consent by Participant | 52 (0.6) | 31 (0.3) | 83 (0.5) |
| Due to SARS-CoV-2 | 33 (0.4) | 27 (0.3) | 60 (0.3) |
| Other | 24 (0.3) | 30 (0.3) | 54 (0.3) |

Percentages are based on the number of randomized subjects.

[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

Randomization Stratum: ≥ 18 and < 65 Years and Not at Risk

| | Placebo (N=8910) n (%) | mRNA-1273 (N=8908) n (%) | Total (N=17818) n (%) |
|--------------------------------------|------------------------------|--------------------------------|-----------------------------|
| Completed Study [1] | 0 | 0 | 0 |
| Discontinued from Study | 107 (1.2) | 76 (0.9) | 183 (1.0) |
| Reason for Discontinuation of Study | | | |
| Adverse Event | 0 | 1 (<0.1) | 1 (<0.1) |
| Serious Adverse Event | 0 | 0 | 0 |
| Death | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Lost to Follow-Up | 30 (0.3) | 17 (0.2) | 47 (0.3) |
| Physician Decision | 0 | 12 (0.1) | 12 (<0.1) |
| Pregnancy | 0 | 0 | 0 |
| Protocol Deviation | 0 | 1 (<0.1) | 1 (<0.1) |
| Study Terminated by Sponsor | 0 | 0 | 0 |
| Withdrawal of Consent by Participant | 72 (0.8) | 39 (0.4) | 111 (0.6) |
| Other | 4 (<0.1) | 5 (<0.1) | 9 (<0.1) |

Percentages are based on the number of randomized subjects.

[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

Randomization Stratum: >=18 and <65 Years and at Risk

| | Placebo (N=2541) n (%) | mRNA-1273 (N=2534) n (%) | Total (N=5075) n (%) |
|---|------------------------------|--------------------------------|----------------------------|
| Number of Subjects | | | |
| Received First Injection | 2535 (99.8) | 2530 (99.8) | 5065 (99.8) |
| Received Second Injection | 2323 (91.4) | 2359 (93.1) | 4682 (92.3) |
| Discontinued Study Vaccine | 45 (1.8) | 24 (0.9) | 69 (1.4) |
| Reason for Discontinuation of Study Vaccine | | | |
| Adverse Event | 3 (0.1) | 3 (0.1) | 6 (0.1) |
| Serious Adverse Event | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Death | 0 | 1 (<0.1) | 1 (<0.1) |
| Lost to Follow-Up | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Physician Decision | 2 (<0.1) | 3 (0.1) | 5 (<0.1) |
| Pregnancy | 0 | 0 | 0 |
| Protocol Deviation | 2 (<0.1) | 0 | 2 (<0.1) |
| Study Terminated by Sponsor | 0 | 0 | 0 |
| Withdrawal of Consent by Participant | 20 (0.8) | 7 (0.3) | 27 (0.5) |
| Due to SARS-CoV-2 | 12 (0.5) | 4 (0.2) | 16 (0.3) |
| Other | 4 (0.2) | 3 (0.1) | 7 (0.1) |

Percentages are based on the number of randomized subjects.

[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

Randomization Stratum: ≥ 18 and < 65 Years and at Risk

| | Placebo (N=2541) n (%) | mRNA-1273 (N=2534) n (%) | Total (N=5075) n (%) |
|--------------------------------------|------------------------------|--------------------------------|----------------------------|
| Completed Study [1] | 0 | 0 | 0 |
| Discontinued from Study | 27 (1.1) | 28 (1.1) | 55 (1.1) |
| Reason for Discontinuation of Study | | | |
| Adverse Event | 0 | 0 | 0 |
| Serious Adverse Event | 0 | 0 | 0 |
| Death | 0 | 1 (<0.1) | 1 (<0.1) |
| Lost to Follow-Up | 1 (<0.1) | 3 (0.1) | 4 (<0.1) |
| Physician Decision | 1 (<0.1) | 4 (0.2) | 5 (<0.1) |
| Pregnancy | 0 | 0 | 0 |
| Protocol Deviation | 0 | 0 | 0 |
| Study Terminated by Sponsor | 0 | 0 | 0 |
| Withdrawal of Consent by Participant | 23 (0.9) | 17 (0.7) | 40 (0.8) |
| Other | 2 (<0.1) | 3 (0.1) | 5 (<0.1) |

Percentages are based on the number of randomized subjects.

[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

Randomization Stratum: >=65 Years

| | Placebo (N=3759) n (%) | mRNA-1273 (N=3766) n (%) | Total (N=7525) n (%) |
|---|------------------------------|--------------------------------|----------------------------|
| Number of Subjects | | | |
| Received First Injection | 3749 (99.7) | 3763 (>99.9) | 7512 (99.8) |
| Received Second Injection | 3565 (94.8) | 3594 (95.4) | 7159 (95.1) |
| Discontinued Study Vaccine | 44 (1.2) | 27 (0.7) | 71 (0.9) |
| Reason for Discontinuation of Study Vaccine | | | |
| Adverse Event | 4 (0.1) | 5 (0.1) | 9 (0.1) |
| Serious Adverse Event | 8 (0.2) | 2 (<0.1) | 10 (0.1) |
| Death | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Lost to Follow-Up | 0 | 0 | 0 |
| Physician Decision | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Pregnancy | 0 | 0 | 0 |
| Protocol Deviation | 1 (<0.1) | 0 | 1 (<0.1) |
| Study Terminated by Sponsor | 0 | 0 | 0 |
| Withdrawal of Consent by Participant | 19 (0.5) | 10 (0.3) | 29 (0.4) |
| Due to SARS-CoV-2 | 4 (0.1) | 4 (0.1) | 8 (0.1) |
| Other | 6 (0.2) | 3 (<0.1) | 9 (0.1) |

Percentages are based on the number of randomized subjects.

[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

Randomization Stratum: >=65 Years

| | Placebo (N=3759) n (%) | mRNA-1273 (N=3766) n (%) | Total (N=7525) n (%) |
|--------------------------------------|------------------------------|--------------------------------|----------------------------|
| Completed Study [1] | 0 | 0 | 0 |
| Discontinued from Study | 34 (0.9) | 16 (0.4) | 50 (0.7) |
| Reason for Discontinuation of Study | | | |
| Adverse Event | 0 | 1 (<0.1) | 1 (<0.1) |
| Serious Adverse Event | 0 | 1 (<0.1) | 1 (<0.1) |
| Death | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Lost to Follow-Up | 0 | 0 | 0 |
| Physician Decision | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Pregnancy | 0 | 0 | 0 |
| Protocol Deviation | 1 (<0.1) | 0 | 1 (<0.1) |
| Study Terminated by Sponsor | 0 | 0 | 0 |
| Withdrawal of Consent by Participant | 25 (0.7) | 11 (0.3) | 36 (0.5) |
| Other | 4 (0.1) | 1 (<0.1) | 5 (<0.1) |

Percentages are based on the number of randomized subjects.

[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

| | Baseline SARS-CoV-2 Negative | | | Baseline SARS-CoV-2 Positive | | | Overall | | |
|-------------------------------|------------------------------|-----------|-----------|------------------------------|-----------|---------|-----------|-----------|-----------|
| | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total |
| | (N=14370) | (N=14312) | (N=28682) | (N=334) | (N=341) | (N=675) | (N=15170) | (N=15180) | (N=30350) |
| Age at Screening (Years) | | | | | | | | | |
| n | 14370 | 14312 | 28682 | 334 | 341 | 675 | 15170 | 15180 | 30350 |
| Mean | 51.4 | 51.5 | 51.5 | 44.8 | 44.1 | 44.5 | 51.3 | 51.4 | 51.4 |
| (SD) | (15.59) | (15.48) | (15.53) | (15.47) | (15.29) | (15.37) | (15.60) | (15.50) | (15.55) |
| Median | 52.0 | 53.0 | 53.0 | 46.0 | 44.0 | 45.0 | 52.0 | 53.0 | 52.0 |
| Min, Max | 18, 95 | 18, 95 | 18, 95 | 18, 83 | 18, 84 | 18, 84 | 18, 95 | 18, 95 | 18, 95 |
| Age Group at Screening, n (%) | | | | | | | | | |
| >=18 and <65 Years | 10773 | 10710 | 21483 | 301 | 306 | 607 | 11418 | 11412 | 22830 |
| | (75.0) | (74.8) | (74.9) | (90.1) | (89.7) | (89.9) | (75.3) | (75.2) | (75.2) |
| >=65 Years | 3597 | 3602 | 7199 | 33 | 35 | 68 | 3752 | 3768 | 7520 |
| | (25.0) | (25.2) | (25.1) | (9.9) | (10.3) | (10.1) | (24.7) | (24.8) | (24.8) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

| | Baseline SARS-CoV-2 Negative | | | Baseline SARS-CoV-2 Positive | | | Overall | | |
|-------------------------------------|------------------------------|------------------------|--------------------|------------------------------|----------------------|------------------|----------------------|------------------------|--------------------|
| | Placebo (N=14370) | mRNA-1273 (N=14312) | Total (N=28682) | Placebo (N=334) | mRNA-1273 (N=341) | Total (N=675) | Placebo (N=15170) | mRNA-1273 (N=15180) | Total (N=30350) |
| Age Subgroup at Screening, n (%) | | | | | | | | | |
| >=18 and <65 Years | 10773 (75.0) | 10710 (74.8) | 21483 (74.9) | 301 (90.1) | 306 (89.7) | 607 (89.9) | 11418 (75.3) | 11412 (75.2) | 22830 (75.2) |
| >=65 and <70 Years | 1749 (12.2) | 1825 (12.8) | 3574 (12.5) | 12 (3.6) | 17 (5.0) | 29 (4.3) | 1817 (12.0) | 1905 (12.5) | 3722 (12.3) |
| >=70 and <75 Years | 1146 (8.0) | 1142 (8.0) | 2288 (8.0) | 10 (3.0) | 11 (3.2) | 21 (3.1) | 1194 (7.9) | 1204 (7.9) | 2398 (7.9) |
| >=75 and <80 Years | 482 (3.4) | 453 (3.2) | 935 (3.3) | 9 (2.7) | 3 (0.9) | 12 (1.8) | 507 (3.3) | 468 (3.1) | 975 (3.2) |
| >=80 Years | 220 (1.5) | 182 (1.3) | 402 (1.4) | 2 (0.6) | 4 (1.2) | 6 (0.9) | 234 (1.5) | 191 (1.3) | 425 (1.4) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

| | Baseline SARS-CoV-2 Negative | | | Baseline SARS-CoV-2 Positive | | | Overall | | |
|--|------------------------------|-----------------|-----------------|------------------------------|---------------|---------------|-----------------|-----------------|-----------------|
| | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total |
| | (N=14370) | (N=14312) | (N=28682) | (N=334) | (N=341) | (N=675) | (N=15170) | (N=15180) | (N=30350) |
| Age Subgroup at Screening, n (%) | | | | | | | | | |
| >=18 and <65 Years | 10773 (75.0) | 10710 (74.8) | 21483 (74.9) | 301 (90.1) | 306 (89.7) | 607 (89.9) | 11418 (75.3) | 11412 (75.2) | 22830 (75.2) |
| >=65 and <75 Years | 2895 (20.1) | 2967 (20.7) | 5862 (20.4) | 22 (6.6) | 28 (8.2) | 50 (7.4) | 3011 (19.8) | 3109 (20.5) | 6120 (20.2) |
| >=75 and <85 Years | 655 (4.6) | 594 (4.2) | 1249 (4.4) | 11 (3.3) | 7 (2.1) | 18 (2.7) | 692 (4.6) | 618 (4.1) | 1310 (4.3) |
| >=85 Years | 47 (0.3) | 41 (0.3) | 88 (0.3) | 0 | 0 | 0 | 49 (0.3) | 41 (0.3) | 90 (0.3) |
| Age and Health Risk for Severe COVID-19, n (%) [1] | | | | | | | | | |
| >=18 and <65 Years and Not at Risk | 8418 (58.6) | 8346 (58.3) | 16764 (58.4) | 238 (71.3) | 259 (76.0) | 497 (73.6) | 8886 (58.6) | 8887 (58.5) | 17773 (58.6) |
| >=18 and <65 Years and at Risk | 2358 (16.4) | 2369 (16.6) | 4727 (16.5) | 63 (18.9) | 47 (13.8) | 110 (16.3) | 2535 (16.7) | 2530 (16.7) | 5065 (16.7) |
| >=65 Years | 3594 (25.0) | 3597 (25.1) | 7191 (25.1) | 33 (9.9) | 35 (10.3) | 68 (10.1) | 3749 (24.7) | 3763 (24.8) | 7512 (24.8) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

| | Baseline SARS-CoV-2 Negative | | | Baseline SARS-CoV-2 Positive | | | Overall | | |
|---|------------------------------|------------------------|--------------------|------------------------------|----------------------|------------------|----------------------|------------------------|--------------------|
| | Placebo (N=14370) | mRNA-1273 (N=14312) | Total (N=28682) | Placebo (N=334) | mRNA-1273 (N=341) | Total (N=675) | Placebo (N=15170) | mRNA-1273 (N=15180) | Total (N=30350) |
| Risk Factor for Severe COVID-19 at Screening, n (%) [2] | | | | | | | | | |
| Chronic Lung Disease | 701 (4.9) | 684 (4.8) | 1385 (4.8) | 11 (3.3) | 8 (2.3) | 19 (2.8) | 741 (4.9) | 707 (4.7) | 1448 (4.8) |
| Significant Cardiac Disease | 702 (4.9) | 699 (4.9) | 1401 (4.9) | 10 (3.0) | 11 (3.2) | 21 (3.1) | 741 (4.9) | 742 (4.9) | 1483 (4.9) |
| Severe Obesity | 920 (6.4) | 924 (6.5) | 1844 (6.4) | 18 (5.4) | 23 (6.7) | 41 (6.1) | 978 (6.4) | 986 (6.5) | 1964 (6.5) |
| Diabetes | 1356 (9.4) | 1360 (9.5) | 2716 (9.5) | 23 (6.9) | 22 (6.5) | 45 (6.7) | 1431 (9.4) | 1427 (9.4) | 2858 (9.4) |
| Liver Disease | 92 (0.6) | 95 (0.7) | 187 (0.7) | 1 (0.3) | 1 (0.3) | 2 (0.3) | 96 (0.6) | 100 (0.7) | 196 (0.6) |
| Human Immunodeficiency Virus Infection | 77 (0.5) | 83 (0.6) | 160 (0.6) | 7 (2.1) | 5 (1.5) | 12 (1.8) | 86 (0.6) | 90 (0.6) | 176 (0.6) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

| | Baseline SARS-CoV-2 Negative | | | Baseline SARS-CoV-2 Positive | | | Overall | | |
|---|------------------------------|-----------------|-----------------|------------------------------|---------------|---------------|-----------------|-----------------|-----------------|
| | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total |
| | (N=14370) | (N=14312) | (N=28682) | (N=334) | (N=341) | (N=675) | (N=15170) | (N=15180) | (N=30350) |
| At Risk for Severe COVID-19 at Screening, n (%) | | | | | | | | | |
| Yes | 3190 (22.2) | 3189 (22.3) | 6379 (22.2) | 63 (18.9) | 55 (16.1) | 118 (17.5) | 3382 (22.3) | 3360 (22.1) | 6742 (22.2) |
| No | 11180 (77.8) | 11123 (77.7) | 22303 (77.8) | 271 (81.1) | 286 (83.9) | 557 (82.5) | 11788 (77.7) | 11820 (77.9) | 23608 (77.8) |
| Baseline RT-PCR Results, n (%) | | | | | | | | | |
| Negative | 14370 (100) | 14312 (100) | 28682 (100) | 236 (70.7) | 252 (73.9) | 488 (72.3) | 14880 (98.1) | 14879 (98.0) | 29759 (98.1) |
| Positive | 0 | 0 | 0 | 95 (28.4) | 87 (25.5) | 182 (27.0) | 95 (0.6) | 87 (0.6) | 182 (0.6) |
| Missing | 0 | 0 | 0 | 3 (0.9) | 2 (0.6) | 5 (0.7) | 195 (1.3) | 214 (1.4) | 409 (1.3) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

| | Baseline SARS-CoV-2 Negative | | | Baseline SARS-CoV-2 Positive | | | Overall | | |
|---------------------------------------|------------------------------|----------------|----------------|------------------------------|---------------|---------------|-----------------|-----------------|-----------------|
| | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total |
| | (N=14370) | (N=14312) | (N=28682) | (N=334) | (N=341) | (N=675) | (N=15170) | (N=15180) | (N=30350) |
| Baseline Elecsys | | | | | | | | | |
| Anti-SARS-CoV-2 Results, n (%) | | | | | | | | | |
| Negative | 14370 (100) | 14312 (100) | 28682 (100) | 34 (10.2) | 36 (10.6) | 70 (10.4) | 14510 (95.6) | 14463 (95.3) | 28973 (95.5) |
| Positive | 0 | 0 | 0 | 299 (89.5) | 303 (88.9) | 602 (89.2) | 299 (2.0) | 303 (2.0) | 602 (2.0) |
| Missing | 0 | 0 | 0 | 1 (0.3) | 2 (0.6) | 3 (0.4) | 361 (2.4) | 414 (2.7) | 775 (2.6) |
| Baseline SARS-CoV-2 Status, n (%) [3] | | | | | | | | | |
| Negative | 14370 (100) | 14312 (100) | 28682 (100) | 0 | 0 | 0 | 14370 (94.7) | 14312 (94.3) | 28682 (94.5) |
| Positive | 0 | 0 | 0 | 334 (100) | 341 (100) | 675 (100) | 334 (2.2) | 341 (2.2) | 675 (2.2) |
| Missing | 0 | 0 | 0 | 0 | 0 | 0 | 466 (3.1) | 527 (3.5) | 993 (3.3) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

| | Baseline SARS-CoV-2 Negative | | | Baseline SARS-CoV-2 Positive | | | Overall | | |
|------------|------------------------------|------------------------|--------------------|------------------------------|----------------------|------------------|----------------------|------------------------|--------------------|
| | Placebo (N=14370) | mRNA-1273 (N=14312) | Total (N=28682) | Placebo (N=334) | mRNA-1273 (N=341) | Total (N=675) | Placebo (N=15170) | mRNA-1273 (N=15180) | Total (N=30350) |
| Sex, n (%) | | | | | | | | | |
| Male | 7641 (53.2) | 7466 (52.2) | 15107 (52.7) | 181 (54.2) | 195 (57.2) | 376 (55.7) | 8067 (53.2) | 7928 (52.2) | 15995 (52.7) |
| Female | 6729 (46.8) | 6846 (47.8) | 13575 (47.3) | 153 (45.8) | 146 (42.8) | 299 (44.3) | 7103 (46.8) | 7252 (47.8) | 14355 (47.3) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

| | Baseline SARS-CoV-2 Negative | | | Baseline SARS-CoV-2 Positive | | | Overall | | |
|---|------------------------------|------------------------|--------------------|------------------------------|----------------------|------------------|----------------------|------------------------|--------------------|
| | Placebo (N=14370) | mRNA-1273 (N=14312) | Total (N=28682) | Placebo (N=334) | mRNA-1273 (N=341) | Total (N=675) | Placebo (N=15170) | mRNA-1273 (N=15180) | Total (N=30350) |
| Race, n (%) | | | | | | | | | |
| White | 11381 (79.2) | 11375 (79.5) | 22756 (79.3) | 224 (67.1) | 219 (64.2) | 443 (65.6) | 11994 (79.1) | 12029 (79.2) | 24023 (79.2) |
| Black or African American | 1397 (9.7) | 1420 (9.9) | 2817 (9.8) | 89 (26.6) | 93 (27.3) | 182 (27.0) | 1528 (10.1) | 1562 (10.3) | 3090 (10.2) |
| Asian | 708 (4.9) | 629 (4.4) | 1337 (4.7) | 5 (1.5) | 10 (2.9) | 15 (2.2) | 732 (4.8) | 653 (4.3) | 1385 (4.6) |
| American Indian or Alaska Native | 113 (0.8) | 109 (0.8) | 222 (0.8) | 2 (0.6) | 0 (0.3) | 2 (0.3) | 120 (0.8) | 110 (0.7) | 230 (0.8) |
| Native Hawaiian or Other Pacific Islander | 30 (0.2) | 33 (0.2) | 63 (0.2) | 1 (0.3) | 0 (0.1) | 1 (0.1) | 32 (0.2) | 34 (0.2) | 66 (0.2) |
| Multiracial | 313 (2.2) | 299 (2.1) | 612 (2.1) | 2 (0.6) | 5 (1.5) | 7 (1.0) | 320 (2.1) | 314 (2.1) | 634 (2.1) |
| Other | 303 (2.1) | 302 (2.1) | 605 (2.1) | 7 (2.1) | 9 (2.6) | 16 (2.4) | 315 (2.1) | 321 (2.1) | 636 (2.1) |
| Not Reported | 71 (0.5) | 89 (0.6) | 160 (0.6) | 4 (1.2) | 4 (1.2) | 8 (1.2) | 75 (0.5) | 99 (0.7) | 174 (0.6) |
| Unknown | 54 (0.4) | 56 (0.4) | 110 (0.4) | 0 | 1 (0.3) | 1 (0.1) | 54 (0.4) | 58 (0.4) | 112 (0.4) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

| | Baseline SARS-CoV-2 Negative | | | Baseline SARS-CoV-2 Positive | | | Overall | | |
|---------------------------------|------------------------------|-----------------|-----------------|------------------------------|---------------|---------------|-----------------|-----------------|-----------------|
| | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total |
| | (N=14370) | (N=14312) | (N=28682) | (N=334) | (N=341) | (N=675) | (N=15170) | (N=15180) | (N=30350) |
| Ethnicity, n (%) | | | | | | | | | |
| Hispanic or Latino | 2885 (20.1) | 2875 (20.1) | 5760 (20.1) | 149 (44.6) | 143 (41.9) | 292 (43.3) | 3114 (20.5) | 3120 (20.6) | 6234 (20.5) |
| Not Hispanic or Latino | 11353 (79.0) | 11301 (79.0) | 22654 (79.0) | 183 (54.8) | 196 (57.5) | 379 (56.1) | 11917 (78.6) | 11917 (78.5) | 23834 (78.5) |
| Not Reported | 79 (0.5) | 97 (0.7) | 176 (0.6) | 2 (0.6) | 2 (0.6) | 4 (0.6) | 84 (0.6) | 104 (0.7) | 188 (0.6) |
| Unknown | 53 (0.4) | 39 (0.3) | 92 (0.3) | 0 | 0 | 0 | 55 (0.4) | 39 (0.3) | 94 (0.3) |
| Race and Ethnicity Group, n (%) | | | | | | | | | |
| [4] | | | | | | | | | |
| Minority | 4287 (29.8) | 4279 (29.9) | 8566 (29.9) | 220 (65.9) | 215 (63.0) | 435 (64.4) | 4632 (30.5) | 4644 (30.6) | 9276 (30.6) |
| Non-minority | 10056 (70.0) | 10010 (69.9) | 20066 (70.0) | 114 (34.1) | 126 (37.0) | 240 (35.6) | 10511 (69.3) | 10510 (69.2) | 21021 (69.3) |
| Missing | 27 (0.2) | 23 (0.2) | 50 (0.2) | 0 | 0 | 0 | 27 (0.2) | 26 (0.2) | 53 (0.2) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

| | Baseline SARS-CoV-2 Negative | | | Baseline SARS-CoV-2 Positive | | | Overall | | |
|---------------------------------|------------------------------|----------------|-----------------|------------------------------|----------------|----------------|----------------|----------------|-----------------|
| | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total |
| | (N=14370) | (N=14312) | (N=28682) | (N=334) | (N=341) | (N=675) | (N=15170) | (N=15180) | (N=30350) |
| Race and Ethnicity Group, n (%) | | | | | | | | | |
| [5] | | | | | | | | | |
| White | 9037 (62.9) | 9075 (63.4) | 18112 (63.1) | 107 (32.0) | 111 (32.6) | 218 (32.3) | 9460 (62.4) | 9532 (62.8) | 18992 (62.6) |
| Communities of Color | 5306 (36.9) | 5214 (36.4) | 10520 (36.7) | 227 (68.0) | 230 (67.4) | 457 (67.7) | 5683 (37.5) | 5622 (37.0) | 11305 (37.2) |
| Missing | 27 (0.2) | 23 (0.2) | 50 (0.2) | 0 | 0 | 0 | 27 (0.2) | 26 (0.2) | 53 (0.2) |
| Weight (kg) | | | | | | | | | |
| n | 14206 | 14138 | 28344 | 334 | 338 | 672 | 14957 | 14948 | 29905 |
| Mean | 85.77 | 85.51 | 85.64 | 85.48 | 87.71 | 86.60 | 85.85 | 85.68 | 85.76 |
| (SD) | (21.612) | (21.936) | (21.774) | (20.989) | (22.313) | (21.678) | (21.642) | (21.982) | (21.812) |
| Median | 82.91 | 82.80 | 82.90 | 81.90 | 84.58 | 83.00 | 83.00 | 83.00 | 83.00 |
| Min, Max | 3.5, 223.0 | 30.3, 236.4 | 3.5, 236.4 | 42.7, 182.4 | 43.2, 179.0 | 42.7, 182.4 | 3.5, 223.0 | 30.3, 236.4 | 3.5, 236.4 |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

| | Baseline SARS-CoV-2 Negative | | | Baseline SARS-CoV-2 Positive | | | Overall | | |
|--------------------------------------|------------------------------|-----------------|-----------------|------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total |
| | (N=14370) | (N=14312) | (N=28682) | (N=334) | (N=341) | (N=675) | (N=15170) | (N=15180) | (N=30350) |
| Height (cm) | | | | | | | | | |
| n | 14206 | 14138 | 28344 | 334 | 338 | 672 | 14957 | 14948 | 29905 |
| Mean | 170.94 | 170.71 | 170.83 | 169.59 | 170.09 | 169.84 | 170.88 | 170.71 | 170.80 |
| (SD) | (10.044) | (9.929) | (9.987) | (10.129) | (9.914) | (10.017) | (10.068) | (9.935) | (10.002) |
| Median | 170.69 | 170.18 | 170.20 | 170.00 | 170.00 | 170.00 | 170.50 | 170.18 | 170.20 |
| Min, Max | 110.6, 223.5 | 104.1, 208.5 | 104.1, 223.5 | 142.2, 198.1 | 147.3, 196.0 | 142.2, 198.1 | 110.6, 223.5 | 104.1, 208.5 | 104.1, 223.5 |
| Body Mass Index (kg/m ²) | | | | | | | | | |
| n | 14204 | 14134 | 28338 | 334 | 338 | 672 | 14955 | 14944 | 29899 |
| Mean | 29.27 | 29.26 | 29.26 | 29.64 | 30.24 | 29.94 | 29.32 | 29.32 | 29.32 |
| (SD) | (6.682) | (6.825) | (6.754) | (6.435) | (7.031) | (6.743) | (6.710) | (6.866) | (6.788) |
| Median | 28.08 | 28.07 | 28.08 | 28.51 | 29.07 | 28.85 | 28.12 | 28.12 | 28.12 |
| Min, Max | 1.5, 87.3 | 10.5, 82.0 | 1.5, 87.3 | 15.7, 59.2 | 15.8, 60.5 | 15.7, 60.5 | 1.5, 87.3 | 10.5, 86.1 | 1.5, 87.3 |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

| | Baseline SARS-CoV-2 Negative | | | Baseline SARS-CoV-2 Positive | | | Overall | | |
|---|------------------------------|------------------------|--------------------|------------------------------|----------------------|------------------|----------------------|------------------------|--------------------|
| | Placebo (N=14370) | mRNA-1273 (N=14312) | Total (N=28682) | Placebo (N=334) | mRNA-1273 (N=341) | Total (N=675) | Placebo (N=15170) | mRNA-1273 (N=15180) | Total (N=30350) |
| Occupational Risk, n (%) [2] | 11811 (82.2) | 11700 (81.7) | 23511 (82.0) | 303 (90.7) | 298 (87.4) | 601 (89.0) | 12491 (82.3) | 12416 (81.8) | 24907 (82.1) |
| Healthcare Workers | 3653 (25.4) | 3620 (25.3) | 7273 (25.4) | 70 (21.0) | 61 (17.9) | 131 (19.4) | 3829 (25.2) | 3784 (24.9) | 7613 (25.1) |
| Emergency Response | 279 (1.9) | 288 (2.0) | 567 (2.0) | 11 (3.3) | 6 (1.8) | 17 (2.5) | 297 (2.0) | 303 (2.0) | 600 (2.0) |
| Retail or Restaurant Operations | 912 (6.3) | 887 (6.2) | 1799 (6.3) | 36 (10.8) | 35 (10.3) | 71 (10.5) | 971 (6.4) | 954 (6.3) | 1925 (6.3) |
| Manufacturing and Production Operations | 399 (2.8) | 390 (2.7) | 789 (2.8) | 10 (3.0) | 22 (6.5) | 32 (4.7) | 420 (2.8) | 426 (2.8) | 846 (2.8) |
| Warehouse Shipping and Fulfillment Centers | 157 (1.1) | 176 (1.2) | 333 (1.2) | 12 (3.6) | 8 (2.3) | 20 (3.0) | 174 (1.1) | 193 (1.3) | 367 (1.2) |
| Transportation and Delivery Services | 440 (3.1) | 445 (3.1) | 885 (3.1) | 19 (5.7) | 28 (8.2) | 47 (7.0) | 473 (3.1) | 485 (3.2) | 958 (3.2) |
| Border Protection and Military Personnel | 66 (0.5) | 63 (0.4) | 129 (0.4) | 1 (0.3) | 1 (0.3) | 2 (0.3) | 68 (0.4) | 69 (0.5) | 137 (0.5) |
| Personal Care and In-Home Services | 430 (3.0) | 430 (3.0) | 860 (3.0) | 25 (7.5) | 27 (7.9) | 52 (7.7) | 470 (3.1) | 469 (3.1) | 939 (3.1) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

| | Baseline SARS-CoV-2 Negative | | | Baseline SARS-CoV-2 Positive | | | Overall | | |
|---|------------------------------|----------------|----------------|------------------------------|--------------|---------------|----------------|----------------|----------------|
| | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total |
| | (N=14370) | (N=14312) | (N=28682) | (N=334) | (N=341) | (N=675) | (N=15170) | (N=15180) | (N=30350) |
| Occupational Risk, n (%) [2] (Cont.) | | | | | | | | | |
| Hospitality and Tourism Workers | 205 (1.4) | 219 (1.5) | 424 (1.5) | 16 (4.8) | 11 (3.2) | 27 (4.0) | 233 (1.5) | 238 (1.6) | 471 (1.6) |
| Pastoral, Social or Public Health Workers | 481 (3.3) | 503 (3.5) | 984 (3.4) | 6 (1.8) | 11 (3.2) | 17 (2.5) | 501 (3.3) | 535 (3.5) | 1036 (3.4) |
| Educators and Students | 1478 (10.3) | 1462 (10.2) | 2940 (10.3) | 25 (7.5) | 26 (7.6) | 51 (7.6) | 1546 (10.2) | 1540 (10.1) | 3086 (10.2) |
| Other | 4531 (31.5) | 4529 (31.6) | 9060 (31.6) | 103 (30.8) | 98 (28.7) | 201 (29.8) | 4797 (31.6) | 4807 (31.7) | 9604 (31.6) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

| | Baseline SARS-CoV-2 Negative | | | Baseline SARS-CoV-2 Positive | | | Overall | | |
|-------------------------------|------------------------------|------------------------|--------------------|------------------------------|----------------------|------------------|----------------------|------------------------|--------------------|
| | Placebo (N=14370) | mRNA-1273 (N=14312) | Total (N=28682) | Placebo (N=334) | mRNA-1273 (N=341) | Total (N=675) | Placebo (N=15170) | mRNA-1273 (N=15180) | Total (N=30350) |
| Location and Living | 11910 | 11878 | 23788 | 303 | 304 | 607 | 12573 | 12599 | 25172 |
| Circumstances Risk, n (%) [2] | (82.9) | (83.0) | (82.9) | (90.7) | (89.1) | (89.9) | (82.9) | (83.0) | (82.9) |
| Resides in Nursing Home or | 28 | 31 | 59 | 1 | 0 | 1 | 29 | 33 | 62 |
| Assisted Living Facility | (0.2) | (0.2) | (0.2) | (0.3) | | (0.1) | (0.2) | (0.2) | (0.2) |
| Resides in Multi-Family | 389 | 437 | 826 | 12 | 13 | 25 | 408 | 462 | 870 |
| Dwelling | (2.7) | (3.1) | (2.9) | (3.6) | (3.8) | (3.7) | (2.7) | (3.0) | (2.9) |
| Resides in High Density | 1229 | 1201 | 2430 | 67 | 60 | 127 | 1304 | 1282 | 2586 |
| Housing | (8.6) | (8.4) | (8.5) | (20.1) | (17.6) | (18.8) | (8.6) | (8.4) | (8.5) |
| Resides in Low Density, | 1384 | 1368 | 2752 | 60 | 68 | 128 | 1475 | 1470 | 2945 |
| Multi-Family Setting | (9.6) | (9.6) | (9.6) | (18.0) | (19.9) | (19.0) | (9.7) | (9.7) | (9.7) |
| Resides in a Single Family | 7872 | 7822 | 15694 | 140 | 136 | 276 | 8311 | 8288 | 16599 |
| Home | (54.8) | (54.7) | (54.7) | (41.9) | (39.9) | (40.9) | (54.8) | (54.6) | (54.7) |
| Other | 2072 | 2092 | 4164 | 51 | 49 | 100 | 2166 | 2184 | 4350 |
| | (14.4) | (14.6) | (14.5) | (15.3) | (14.4) | (14.8) | (14.3) | (14.4) | (14.3) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|-------------------------------|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=11418) | mRNA-1273 (N=11412) | Total (N=22830) | Placebo (N=3752) | mRNA-1273 (N=3768) | Total (N=7520) | Placebo (N=15170) | mRNA-1273 (N=15180) | Total (N=30350) |
| Age at Screening (Years) | | | | | | | | | |
| n | 11418 | 11412 | 22830 | 3752 | 3768 | 7520 | 15170 | 15180 | 30350 |
| Mean | 45.0 | 45.1 | 45.0 | 70.7 | 70.4 | 70.6 | 51.3 | 51.4 | 51.4 |
| (SD) | (12.30) | (12.35) | (12.32) | (4.88) | (4.66) | (4.77) | (15.60) | (15.50) | (15.55) |
| Median | 46.0 | 46.0 | 46.0 | 70.0 | 69.0 | 70.0 | 52.0 | 53.0 | 52.0 |
| Min, Max | 18, 64 | 18, 64 | 18, 64 | 65, 95 | 65, 95 | 65, 95 | 18, 95 | 18, 95 | 18, 95 |
| Age Group at Screening, n (%) | | | | | | | | | |
| >=18 and <65 Years | 11418 (100) | 11412 (100) | 22830 (100) | 0 | 0 | 0 | 11418 (75.3) | 11412 (75.2) | 22830 (75.2) |
| >=65 Years | 0 | 0 | 0 | 3752 (100) | 3768 (100) | 7520 (100) | 3752 (24.7) | 3768 (24.8) | 7520 (24.8) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|-------------------------------------|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=11418) | mRNA-1273 (N=11412) | Total (N=22830) | Placebo (N=3752) | mRNA-1273 (N=3768) | Total (N=7520) | Placebo (N=15170) | mRNA-1273 (N=15180) | Total (N=30350) |
| Age Subgroup at Screening, n (%) | | | | | | | | | |
| >=18 and <65 Years | 11418 (100) | 11412 (100) | 22830 (100) | 0 | 0 | 0 | 11418 (75.3) | 11412 (75.2) | 22830 (75.2) |
| >=65 and <70 Years | 0 | 0 | 0 | 1817 (48.4) | 1905 (50.6) | 3722 (49.5) | 1817 (12.0) | 1905 (12.5) | 3722 (12.3) |
| >=70 and <75 Years | 0 | 0 | 0 | 1194 (31.8) | 1204 (32.0) | 2398 (31.9) | 1194 (7.9) | 1204 (7.9) | 2398 (7.9) |
| >=75 and <80 Years | 0 | 0 | 0 | 507 (13.5) | 468 (12.4) | 975 (13.0) | 507 (3.3) | 468 (3.1) | 975 (3.2) |
| >=80 Years | 0 | 0 | 0 | 234 (6.2) | 191 (5.1) | 425 (5.7) | 234 (1.5) | 191 (1.3) | 425 (1.4) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|---|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=11418) | mRNA-1273 (N=11412) | Total (N=22830) | Placebo (N=3752) | mRNA-1273 (N=3768) | Total (N=7520) | Placebo (N=15170) | mRNA-1273 (N=15180) | Total (N=30350) |
| Age Subgroup at Screening, n (%) | | | | | | | | | |
| >=18 and <65 Years | 11418 (100) | 11412 (100) | 22830 (100) | 0 | 0 | 0 | 11418 (75.3) | 11412 (75.2) | 22830 (75.2) |
| >=65 and <75 Years | 0 | 0 | 0 | 3011 (80.3) | 3109 (82.5) | 6120 (81.4) | 3011 (19.8) | 3109 (20.5) | 6120 (20.2) |
| >=75 and <85 Years | 0 | 0 | 0 | 692 (18.4) | 618 (16.4) | 1310 (17.4) | 692 (4.6) | 618 (4.1) | 1310 (4.3) |
| >=85 Years | 0 | 0 | 0 | 49 (1.3) | 41 (1.1) | 90 (1.2) | 49 (0.3) | 41 (0.3) | 90 (0.3) |
| Age and Health Risk for Severe COVID-19, n (%) [1] | | | | | | | | | |
| >=18 and <65 Years and Not at Risk | 8885 (77.8) | 8887 (77.9) | 17772 (77.8) | 1 (<0.1) | 0 | 1 (<0.1) | 8886 (58.6) | 8887 (58.5) | 17773 (58.6) |
| >=18 and <65 Years and at Risk | 2532 (22.2) | 2524 (22.1) | 5056 (22.1) | 3 (<0.1) | 6 (0.2) | 9 (0.1) | 2535 (16.7) | 2530 (16.7) | 5065 (16.7) |
| >=65 Years | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) | 3748 (99.9) | 3762 (99.8) | 7510 (99.9) | 3749 (24.7) | 3763 (24.8) | 7512 (24.8) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|--|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=11418) | mRNA-1273 (N=11412) | Total (N=22830) | Placebo (N=3752) | mRNA-1273 (N=3768) | Total (N=7520) | Placebo (N=15170) | mRNA-1273 (N=15180) | Total (N=30350) |
| Risk Factor for Severe COVID-19 at Screening, n (%) [2] | | | | | | | | | |
| Chronic Lung Disease | 500 (4.4) | 471 (4.1) | 971 (4.3) | 241 (6.4) | 236 (6.3) | 477 (6.3) | 741 (4.9) | 707 (4.7) | 1448 (4.8) |
| Significant Cardiac Disease | 296 (2.6) | 310 (2.7) | 606 (2.7) | 445 (11.9) | 432 (11.5) | 877 (11.7) | 741 (4.9) | 742 (4.9) | 1483 (4.9) |
| Severe Obesity | 855 (7.5) | 846 (7.4) | 1701 (7.5) | 123 (3.3) | 140 (3.7) | 263 (3.5) | 978 (6.4) | 986 (6.5) | 1964 (6.5) |
| Diabetes | 897 (7.9) | 900 (7.9) | 1797 (7.9) | 534 (14.2) | 527 (14.0) | 1061 (14.1) | 1431 (9.4) | 1427 (9.4) | 2858 (9.4) |
| Liver Disease | 70 (0.6) | 82 (0.7) | 152 (0.7) | 26 (0.7) | 18 (0.5) | 44 (0.6) | 96 (0.6) | 100 (0.7) | 196 (0.6) |
| Human Immunodeficiency Virus Infection | 72 (0.6) | 75 (0.7) | 147 (0.6) | 14 (0.4) | 15 (0.4) | 29 (0.4) | 86 (0.6) | 90 (0.6) | 176 (0.6) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|---|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=11418) | mRNA-1273 (N=11412) | Total (N=22830) | Placebo (N=3752) | mRNA-1273 (N=3768) | Total (N=7520) | Placebo (N=15170) | mRNA-1273 (N=15180) | Total (N=30350) |
| At Risk for Severe COVID-19 at Screening, n (%) | | | | | | | | | |
| Yes | 2283 (20.0) | 2275 (19.9) | 4558 (20.0) | 1099 (29.3) | 1085 (28.8) | 2184 (29.0) | 3382 (22.3) | 3360 (22.1) | 6742 (22.2) |
| No | 9135 (80.0) | 9137 (80.1) | 18272 (80.0) | 2653 (70.7) | 2683 (71.2) | 5336 (71.0) | 11788 (77.7) | 11820 (77.9) | 23608 (77.8) |
| Baseline RT-PCR Results, n (%) | | | | | | | | | |
| Negative | 11192 (98.0) | 11172 (97.9) | 22364 (98.0) | 3688 (98.3) | 3707 (98.4) | 7395 (98.3) | 14880 (98.1) | 14879 (98.0) | 29759 (98.1) |
| Positive | 85 (0.7) | 80 (0.7) | 165 (0.7) | 10 (0.3) | 7 (0.2) | 17 (0.2) | 95 (0.6) | 87 (0.6) | 182 (0.6) |
| Missing | 141 (1.2) | 160 (1.4) | 301 (1.3) | 54 (1.4) | 54 (1.4) | 108 (1.4) | 195 (1.3) | 214 (1.4) | 409 (1.3) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|--|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=11418) | mRNA-1273 (N=11412) | Total (N=22830) | Placebo (N=3752) | mRNA-1273 (N=3768) | Total (N=7520) | Placebo (N=15170) | mRNA-1273 (N=15180) | Total (N=30350) |
| Baseline Elecsys | | | | | | | | | |
| Anti-SARS-CoV-2 Results, n (%) | | | | | | | | | |
| Negative | 10878 (95.3) | 10828 (94.9) | 21706 (95.1) | 3632 (96.8) | 3635 (96.5) | 7267 (96.6) | 14510 (95.6) | 14463 (95.3) | 28973 (95.5) |
| Positive | 271 (2.4) | 271 (2.4) | 542 (2.4) | 28 (0.7) | 32 (0.8) | 60 (0.8) | 299 (2.0) | 303 (2.0) | 602 (2.0) |
| Missing | 269 (2.4) | 313 (2.7) | 582 (2.5) | 92 (2.5) | 101 (2.7) | 193 (2.6) | 361 (2.4) | 414 (2.7) | 775 (2.6) |
| Baseline SARS-CoV-2 Status, n (%) [3] | | | | | | | | | |
| Negative | 10773 (94.4) | 10710 (93.8) | 21483 (94.1) | 3597 (95.9) | 3602 (95.6) | 7199 (95.7) | 14370 (94.7) | 14312 (94.3) | 28682 (94.5) |
| Positive | 301 (2.6) | 306 (2.7) | 607 (2.7) | 33 (0.9) | 35 (0.9) | 68 (0.9) | 334 (2.2) | 341 (2.2) | 675 (2.2) |
| Missing | 344 (3.0) | 396 (3.5) | 740 (3.2) | 122 (3.3) | 131 (3.5) | 253 (3.4) | 466 (3.1) | 527 (3.5) | 993 (3.3) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|------------|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=11418) | mRNA-1273 (N=11412) | Total (N=22830) | Placebo (N=3752) | mRNA-1273 (N=3768) | Total (N=7520) | Placebo (N=15170) | mRNA-1273 (N=15180) | Total (N=30350) |
| Sex, n (%) | | | | | | | | | |
| Male | 5962 (52.2) | 5850 (51.3) | 11812 (51.7) | 2105 (56.1) | 2078 (55.1) | 4183 (55.6) | 8067 (53.2) | 7928 (52.2) | 15995 (52.7) |
| Female | 5456 (47.8) | 5562 (48.7) | 11018 (48.3) | 1647 (43.9) | 1690 (44.9) | 3337 (44.4) | 7103 (46.8) | 7252 (47.8) | 14355 (47.3) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|---|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=11418) | mRNA-1273 (N=11412) | Total (N=22830) | Placebo (N=3752) | mRNA-1273 (N=3768) | Total (N=7520) | Placebo (N=15170) | mRNA-1273 (N=15180) | Total (N=30350) |
| Race, n (%) | | | | | | | | | |
| White | 8653 (75.8) | 8652 (75.8) | 17305 (75.8) | 3341 (89.0) | 3377 (89.6) | 6718 (89.3) | 11994 (79.1) | 12029 (79.2) | 24023 (79.2) |
| Black or African American | 1314 (11.5) | 1341 (11.8) | 2655 (11.6) | 214 (5.7) | 221 (5.9) | 435 (5.8) | 1528 (10.1) | 1562 (10.3) | 3090 (10.2) |
| Asian | 655 (5.7) | 587 (5.1) | 1242 (5.4) | 77 (2.1) | 66 (1.8) | 143 (1.9) | 732 (4.8) | 653 (4.3) | 1385 (4.6) |
| American Indian or Alaska Native | 94 (0.8) | 89 (0.8) | 183 (0.8) | 26 (0.7) | 21 (0.6) | 47 (0.6) | 120 (0.8) | 110 (0.7) | 230 (0.8) |
| Native Hawaiian or Other Pacific Islander | 29 (0.3) | 31 (0.3) | 60 (0.3) | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) | 32 (0.2) | 34 (0.2) | 66 (0.2) |
| Multiracial | 282 (2.5) | 280 (2.5) | 562 (2.5) | 38 (1.0) | 34 (0.9) | 72 (1.0) | 320 (2.1) | 314 (2.1) | 634 (2.1) |
| Other | 283 (2.5) | 294 (2.6) | 577 (2.5) | 32 (0.9) | 27 (0.7) | 59 (0.8) | 315 (2.1) | 321 (2.1) | 636 (2.1) |
| Not Reported | 62 (0.5) | 86 (0.8) | 148 (0.6) | 13 (0.3) | 13 (0.3) | 26 (0.3) | 75 (0.5) | 99 (0.7) | 174 (0.6) |
| Unknown | 46 (0.4) | 52 (0.5) | 98 (0.4) | 8 (0.2) | 6 (0.2) | 14 (0.2) | 54 (0.4) | 58 (0.4) | 112 (0.4) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
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- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|---------------------------------|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=11418) | mRNA-1273 (N=11412) | Total (N=22830) | Placebo (N=3752) | mRNA-1273 (N=3768) | Total (N=7520) | Placebo (N=15170) | mRNA-1273 (N=15180) | Total (N=30350) |
| Ethnicity, n (%) | | | | | | | | | |
| Hispanic or Latino | 2779 (24.3) | 2765 (24.2) | 5544 (24.3) | 335 (8.9) | 355 (9.4) | 690 (9.2) | 3114 (20.5) | 3120 (20.6) | 6234 (20.5) |
| Not Hispanic or Latino | 8542 (74.8) | 8548 (74.9) | 17090 (74.9) | 3375 (90.0) | 3369 (89.4) | 6744 (89.7) | 11917 (78.6) | 11917 (78.5) | 23834 (78.5) |
| Not Reported | 58 (0.5) | 72 (0.6) | 130 (0.6) | 26 (0.7) | 32 (0.8) | 58 (0.8) | 84 (0.6) | 104 (0.7) | 188 (0.6) |
| Unknown | 39 (0.3) | 27 (0.2) | 66 (0.3) | 16 (0.4) | 12 (0.3) | 28 (0.4) | 55 (0.4) | 39 (0.3) | 94 (0.3) |
| Race and Ethnicity Group, n (%) | | | | | | | | | |
| [4] | | | | | | | | | |
| Minority | 4072 (35.7) | 4065 (35.6) | 8137 (35.6) | 560 (14.9) | 579 (15.4) | 1139 (15.1) | 4632 (30.5) | 4644 (30.6) | 9276 (30.6) |
| Non-minority | 7332 (64.2) | 7327 (64.2) | 14659 (64.2) | 3179 (84.7) | 3183 (84.5) | 6362 (84.6) | 10511 (69.3) | 10510 (69.2) | 21021 (69.3) |
| Missing | 14 (0.1) | 20 (0.2) | 34 (0.1) | 13 (0.3) | 6 (0.2) | 19 (0.3) | 27 (0.2) | 26 (0.2) | 53 (0.2) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
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- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|---------------------------------|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=11418) | mRNA-1273 (N=11412) | Total (N=22830) | Placebo (N=3752) | mRNA-1273 (N=3768) | Total (N=7520) | Placebo (N=15170) | mRNA-1273 (N=15180) | Total (N=30350) |
| Race and Ethnicity Group, n (%) | | | | | | | | | |
| [5] | | | | | | | | | |
| White | 6396 (56.0) | 6461 (56.6) | 12857 (56.3) | 3064 (81.7) | 3071 (81.5) | 6135 (81.6) | 9460 (62.4) | 9532 (62.8) | 18992 (62.6) |
| Communities of Color | 5008 (43.9) | 4931 (43.2) | 9939 (43.5) | 675 (18.0) | 691 (18.3) | 1366 (18.2) | 5683 (37.5) | 5622 (37.0) | 11305 (37.2) |
| Missing | 14 (0.1) | 20 (0.2) | 34 (0.1) | 13 (0.3) | 6 (0.2) | 19 (0.3) | 27 (0.2) | 26 (0.2) | 53 (0.2) |
| Weight (kg) | | | | | | | | | |
| n | 11255 | 11240 | 22495 | 3702 | 3708 | 7410 | 14957 | 14948 | 29905 |
| Mean | 86.73 | 86.52 | 86.63 | 83.16 | 83.13 | 83.15 | 85.85 | 85.68 | 85.76 |
| (SD) | (22.399) | (22.694) | (22.547) | (18.906) | (19.448) | (19.178) | (21.642) | (21.982) | (21.812) |
| Median | 83.64 | 83.64 | 83.64 | 81.60 | 81.21 | 81.36 | 83.00 | 83.00 | 83.00 |
| Min, Max | 3.5, 223.0 | 30.3, 236.4 | 3.5, 236.4 | 34.8, 184.5 | 31.5, 168.6 | 31.5, 184.5 | 3.5, 223.0 | 30.3, 236.4 | 3.5, 236.4 |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
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- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|--------------------------------------|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=11418) | mRNA-1273 (N=11412) | Total (N=22830) | Placebo (N=3752) | mRNA-1273 (N=3768) | Total (N=7520) | Placebo (N=15170) | mRNA-1273 (N=15180) | Total (N=30350) |
| Height (cm) | | | | | | | | | |
| n | 11255 | 11239 | 22494 | 3702 | 3709 | 7411 | 14957 | 14948 | 29905 |
| Mean | 171.16 | 170.96 | 171.06 | 170.05 | 169.95 | 170.00 | 170.88 | 170.71 | 170.80 |
| (SD) | (9.999) | (9.895) | (9.948) | (10.232) | (10.017) | (10.124) | (10.068) | (9.935) | (10.002) |
| Median | 171.00 | 170.18 | 170.50 | 170.18 | 170.18 | 170.18 | 170.50 | 170.18 | 170.20 |
| Min, Max | 110.6, 205.7 | 104.1, 208.5 | 104.1, 208.5 | 124.5, 223.5 | 123.0, 208.3 | 123.0, 223.5 | 110.6, 223.5 | 104.1, 208.5 | 104.1, 223.5 |
| Body Mass Index (kg/m ²) | | | | | | | | | |
| n | 11254 | 11236 | 22490 | 3701 | 3708 | 7409 | 14955 | 14944 | 29899 |
| Mean | 29.52 | 29.53 | 29.53 | 28.69 | 28.69 | 28.69 | 29.32 | 29.32 | 29.32 |
| (SD) | (6.956) | (7.135) | (7.046) | (5.856) | (5.932) | (5.894) | (6.710) | (6.866) | (6.788) |
| Median | 28.27 | 28.25 | 28.26 | 27.70 | 27.86 | 27.78 | 28.12 | 28.12 | 28.12 |
| Min, Max | 1.5, 87.3 | 10.5, 86.1 | 1.5, 87.3 | 12.1, 71.1 | 11.2, 66.7 | 11.2, 71.1 | 1.5, 87.3 | 10.5, 86.1 | 1.5, 87.3 |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|---|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=11418) | mRNA-1273 (N=11412) | Total (N=22830) | Placebo (N=3752) | mRNA-1273 (N=3768) | Total (N=7520) | Placebo (N=15170) | mRNA-1273 (N=15180) | Total (N=30350) |
| Occupational Risk, n (%) [2] | 10112 (88.6) | 10057 (88.1) | 20169 (88.3) | 2379 (63.4) | 2359 (62.6) | 4738 (63.0) | 12491 (82.3) | 12416 (81.8) | 24907 (82.1) |
| Healthcare Workers | 3325 (29.1) | 3323 (29.1) | 6648 (29.1) | 504 (13.4) | 461 (12.2) | 965 (12.8) | 3829 (25.2) | 3784 (24.9) | 7613 (25.1) |
| Emergency Response | 278 (2.4) | 282 (2.5) | 560 (2.5) | 19 (0.5) | 21 (0.6) | 40 (0.5) | 297 (2.0) | 303 (2.0) | 600 (2.0) |
| Retail or Restaurant Operations | 872 (7.6) | 854 (7.5) | 1726 (7.6) | 99 (2.6) | 100 (2.7) | 199 (2.6) | 971 (6.4) | 954 (6.3) | 1925 (6.3) |
| Manufacturing and Production Operations | 390 (3.4) | 392 (3.4) | 782 (3.4) | 30 (0.8) | 34 (0.9) | 64 (0.9) | 420 (2.8) | 426 (2.8) | 846 (2.8) |
| Warehouse Shipping and Fulfillment Centers | 162 (1.4) | 184 (1.6) | 346 (1.5) | 12 (0.3) | 9 (0.2) | 21 (0.3) | 174 (1.1) | 193 (1.3) | 367 (1.2) |
| Transportation and Delivery Services | 412 (3.6) | 435 (3.8) | 847 (3.7) | 61 (1.6) | 50 (1.3) | 111 (1.5) | 473 (3.1) | 485 (3.2) | 958 (3.2) |
| Border Protection and Military Personnel | 62 (0.5) | 66 (0.6) | 128 (0.6) | 6 (0.2) | 3 (<0.1) | 9 (0.1) | 68 (0.4) | 69 (0.5) | 137 (0.5) |
| Personal Care and In-Home Services | 409 (3.6) | 402 (3.5) | 811 (3.6) | 61 (1.6) | 67 (1.8) | 128 (1.7) | 470 (3.1) | 469 (3.1) | 939 (3.1) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|--|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=11418) | mRNA-1273 (N=11412) | Total (N=22830) | Placebo (N=3752) | mRNA-1273 (N=3768) | Total (N=7520) | Placebo (N=15170) | mRNA-1273 (N=15180) | Total (N=30350) |
| Occupational Risk, n (%) [2] (Cont.) | | | | | | | | | |
| Hospitality and Tourism Workers | 189 (1.7) | 202 (1.8) | 391 (1.7) | 44 (1.2) | 36 (1.0) | 80 (1.1) | 233 (1.5) | 238 (1.6) | 471 (1.6) |
| Pastoral, Social or Public Health Workers | 362 (3.2) | 387 (3.4) | 749 (3.3) | 139 (3.7) | 148 (3.9) | 287 (3.8) | 501 (3.3) | 535 (3.5) | 1036 (3.4) |
| Educators and Students | 1377 (12.1) | 1356 (11.9) | 2733 (12.0) | 169 (4.5) | 184 (4.9) | 353 (4.7) | 1546 (10.2) | 1540 (10.1) | 3086 (10.2) |
| Other | 3375 (29.6) | 3380 (29.6) | 6755 (29.6) | 1422 (37.9) | 1427 (37.9) | 2849 (37.9) | 4797 (31.6) | 4807 (31.7) | 9604 (31.6) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|-------------------------------|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=11418) | mRNA-1273 (N=11412) | Total (N=22830) | Placebo (N=3752) | mRNA-1273 (N=3768) | Total (N=7520) | Placebo (N=15170) | mRNA-1273 (N=15180) | Total (N=30350) |
| Location and Living | 9486 | 9488 | 18974 | 3087 | 3111 | 6198 | 12573 | 12599 | 25172 |
| Circumstances Risk, n (%) [2] | (83.1) | (83.1) | (83.1) | (82.3) | (82.6) | (82.4) | (82.9) | (83.0) | (82.9) |
| Resides in Nursing Home or | 9 | 22 | 31 | 20 | 11 | 31 | 29 | 33 | 62 |
| Assisted Living Facility | (<0.1) | (0.2) | (0.1) | (0.5) | (0.3) | (0.4) | (0.2) | (0.2) | (0.2) |
| Resides in Multi-Family | 345 | 396 | 741 | 63 | 66 | 129 | 408 | 462 | 870 |
| Dwelling | (3.0) | (3.5) | (3.2) | (1.7) | (1.8) | (1.7) | (2.7) | (3.0) | (2.9) |
| Resides in High Density | 1064 | 1031 | 2095 | 240 | 251 | 491 | 1304 | 1282 | 2586 |
| Housing | (9.3) | (9.0) | (9.2) | (6.4) | (6.7) | (6.5) | (8.6) | (8.4) | (8.5) |
| Resides in Low Density, | 1221 | 1228 | 2449 | 254 | 242 | 496 | 1475 | 1470 | 2945 |
| Multi-Family Setting | (10.7) | (10.8) | (10.7) | (6.8) | (6.4) | (6.6) | (9.7) | (9.7) | (9.7) |
| Resides in a Single Family | 6072 | 6025 | 12097 | 2239 | 2263 | 4502 | 8311 | 8288 | 16599 |
| Home | (53.2) | (52.8) | (53.0) | (59.7) | (60.1) | (59.9) | (54.8) | (54.6) | (54.7) |
| Other | 1636 | 1638 | 3274 | 530 | 546 | 1076 | 2166 | 2184 | 4350 |
| | (14.3) | (14.4) | (14.3) | (14.1) | (14.5) | (14.3) | (14.3) | (14.4) | (14.3) |

Percentages are based on the number of subjects in Full Analysis Set.

- [1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
- [2] Subjects could be under one or more categories, and are counted once at each category.
- [3] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
- [4] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
- [5] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

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Table 14.1.6.2
Summary of Study Duration
Safety Set

| | Placebo (N=15165) | mRNA-1273 (N=15184) | Total (N=30350) |
|---|----------------------|------------------------|--------------------|
| Number of Subjects, n (%) | | | |
| Received First Injection | 15165 (100) | 15184 (100) | 30350 (100) |
| Received Second Injection | 13913 (91.7) | 13985 (92.1) | 27898 (91.9) |
| >= 28 Days Since Second Injection | 11999 (79.1) | 12136 (79.9) | 24135 (79.5) |
| >= 56 Days Since Second Injection | 5048 (33.3) | 5131 (33.8) | 10179 (33.5) |
| Study Duration from Randomization (Days) | | | |
| Mean (SD) | 74.9 (20.75) | 75.0 (20.73) | 74.9 (20.74) |
| Median | 78.0+ | 78.0+ | 78.0+ |
| Q1, Q3 | 63.0+, 91.0+ | 63.0+, 91.0+ | 63.0+, 91.0+ |
| Min, Max | 1+, 108+ | 4+, 108+ | 1+, 108+ |
| Study Duration from First Injection (Days) | | | |
| Mean (SD) | 74.9 (20.75) | 74.9 (20.73) | 74.9 (20.74) |
| Median | 78.0+ | 78.0+ | 78.0+ |
| Q1, Q3 | 63.0+, 91.0+ | 63.0+, 91.0+ | 63.0+, 91.0+ |
| Min, Max | 1+, 108+ | 4+, 108+ | 1+, 108+ |
| Study Duration from Second Injection (Days) [1] | | | |
| Mean (SD) | 44.5 (21.28) | 44.8 (21.16) | 44.7 (21.22) |
| Median | 49.0+ | 49.0+ | 49.0+ |
| Q1, Q3 | 31.0+, 59.0+ | 34.0+, 61.0+ | 33.0+, 61.0+ |
| Min, Max | 0+, 83+ | 0+, 83+ | 0+, 83+ |

+ indicates ongoing subjects.

Percentages are based on the number of safety subjects.

[1] Study duration from second injection is 0 day for subjects who did not receive second injection.

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Table 14.1.6.2
Summary of Study Duration
Safety Set

| | Placebo (N=15165) | mRNA-1273 (N=15184) | Total (N=30350) |
|--|----------------------|------------------------|--------------------|
| Study Duration from Second Injection in Subjects Who Received Second Injection (Days) | | | |
| n | 13913 | 13985 | 27898 |
| Mean (SD) | 48.5 (17.30) | 48.7 (17.29) | 48.6 (17.30) |
| Median | 50.0+ | 50.0+ | 50.0+ |
| Q1, Q3 | 37.0+, 62.0+ | 37.0+, 62.0+ | 37.0+, 62.0+ |
| Min, Max | 1+, 83+ | 1+, 83+ | 1+, 83+ |

+ indicates ongoing subjects.

Percentages are based on the number of safety subjects.

[1] Study duration from second injection is 0 day for subjects who did not receive second injection.

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Table 14.3.1.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=15154) n (%) | mRNA-1273 (N=15167) n (%) | Total (N=30322) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Solicited Adverse Reactions - N1 | 15154 | 15167 | 30322 |
| Any Solicited Adverse Reactions | 7282 (48.1) | 13320 (87.8) | 20602 (67.9) |
| 95% CI | 47.3, 48.9 | 87.3, 88.3 | 67.4, 68.5 |
| Grade 1 | 5145 (34.0) | 9339 (61.6) | 14484 (47.8) |
| Grade 2 | 1769 (11.7) | 3128 (20.6) | 4897 (16.1) |
| Grade 3 | 362 (2.4) | 848 (5.6) | 1210 (4.0) |
| Grade 4 | 6 (<0.1) | 5 (<0.1) | 11 (<0.1) |
| Solicited Local Adverse Reactions - N1 | 15150 | 15163 | 30314 |
| Any Solicited Local Adverse Reactions | 2998 (19.8) | 12765 (84.2) | 15763 (52.0) |
| 95% CI | 19.2, 20.4 | 83.6, 84.8 | 51.4, 52.6 |
| Grade 1 | 2839 (18.7) | 10728 (70.8) | 13567 (44.8) |
| Grade 2 | 81 (0.5) | 1508 (9.9) | 1589 (5.2) |
| Grade 3 | 78 (0.5) | 529 (3.5) | 607 (2.0) |
| Grade 4 | 0 | 0 | 0 |
| Pain - N1 | 15150 | 15163 | 30314 |
| Any | 2660 (17.6) | 12690 (83.7) | 15350 (50.6) |
| Grade 1 | 2552 (16.8) | 10987 (72.5) | 13539 (44.7) |
| Grade 2 | 53 (0.3) | 1286 (8.5) | 1339 (4.4) |
| Grade 3 | 55 (0.4) | 417 (2.8) | 472 (1.6) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=15154) n (%) | mRNA-1273 (N=15167) n (%) | Total (N=30322) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Erythema (Redness) - N1 | 15150 | 15162 | 30313 |
| Any | 65 (0.4) | 431 (2.8) | 496 (1.6) |
| Grade 1 | 45 (0.3) | 268 (1.8) | 313 (1.0) |
| Grade 2 | 7 (<0.1) | 121 (0.8) | 128 (0.4) |
| Grade 3 | 13 (<0.1) | 42 (0.3) | 55 (0.2) |
| Grade 4 | 0 | 0 | 0 |
| Swelling (Hardness) - N1 | 15150 | 15162 | 30313 |
| Any | 52 (0.3) | 934 (6.2) | 986 (3.3) |
| Grade 1 | 39 (0.3) | 608 (4.0) | 647 (2.1) |
| Grade 2 | 7 (<0.1) | 244 (1.6) | 251 (0.8) |
| Grade 3 | 6 (<0.1) | 82 (0.5) | 88 (0.3) |
| Grade 4 | 0 | 0 | 0 |
| Lymphadenopathy - N1 [1] | 15150 | 15162 | 30313 |
| Any | 722 (4.8) | 1553 (10.2) | 2275 (7.5) |
| Grade 1 | 669 (4.4) | 1395 (9.2) | 2064 (6.8) |
| Grade 2 | 26 (0.2) | 110 (0.7) | 136 (0.4) |
| Grade 3 | 27 (0.2) | 48 (0.3) | 75 (0.2) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=15154) n (%) | mRNA-1273 (N=15167) n (%) | Total (N=30322) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Solicited Systemic Adverse Reactions - N1 | 15154 | 15166 | 30321 |
| Any Solicited Systemic Adverse Reactions | 6398 (42.2) | 8321 (54.9) | 14719 (48.5) |
| 95% CI | 41.4, 43.0 | 54.1, 55.7 | 48.0, 49.1 |
| Grade 1 | 4345 (28.7) | 5370 (35.4) | 9715 (32.0) |
| Grade 2 | 1738 (11.5) | 2499 (16.5) | 4237 (14.0) |
| Grade 3 | 309 (2.0) | 447 (2.9) | 756 (2.5) |
| Grade 4 | 6 (<0.1) | 5 (<0.1) | 11 (<0.1) |
| Fever - N1 | 15152 | 15163 | 30316 |
| Any | 46 (0.3) | 115 (0.8) | 161 (0.5) |
| Grade 1 | 31 (0.2) | 74 (0.5) | 105 (0.3) |
| Grade 2 | 7 (<0.1) | 26 (0.2) | 33 (0.1) |
| Grade 3 | 2 (<0.1) | 11 (<0.1) | 13 (<0.1) |
| Grade 4 | 6 (<0.1) | 4 (<0.1) | 10 (<0.1) |
| Headache - N1 | 15149 | 15162 | 30312 |
| Any | 4027 (26.6) | 4952 (32.7) | 8979 (29.6) |
| Grade 1 | 3304 (21.8) | 3953 (26.1) | 7257 (23.9) |
| Grade 2 | 527 (3.5) | 728 (4.8) | 1255 (4.1) |
| Grade 3 | 196 (1.3) | 271 (1.8) | 467 (1.5) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=15154) n (%) | mRNA-1273 (N=15167) n (%) | Total (N=30322) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Fatigue - N1 | 15149 | 15162 | 30312 |
| Any | 4133 (27.3) | 5635 (37.2) | 9768 (32.2) |
| Grade 1 | 2708 (17.9) | 3599 (23.7) | 6307 (20.8) |
| Grade 2 | 1319 (8.7) | 1885 (12.4) | 3204 (10.6) |
| Grade 3 | 106 (0.7) | 150 (1.0) | 256 (0.8) |
| Grade 4 | 0 | 1 (<0.1) | 1 (<0.1) |
| Myalgia - N1 | 15149 | 15162 | 30312 |
| Any | 2069 (13.7) | 3441 (22.7) | 5510 (18.2) |
| Grade 1 | 1566 (10.3) | 2444 (16.1) | 4010 (13.2) |
| Grade 2 | 456 (3.0) | 907 (6.0) | 1363 (4.5) |
| Grade 3 | 47 (0.3) | 90 (0.6) | 137 (0.5) |
| Grade 4 | 0 | 0 | 0 |
| Arthralgia - N1 | 15149 | 15162 | 30312 |
| Any | 1783 (11.8) | 2510 (16.6) | 4293 (14.2) |
| Grade 1 | 1342 (8.9) | 1844 (12.2) | 3186 (10.5) |
| Grade 2 | 404 (2.7) | 605 (4.0) | 1009 (3.3) |
| Grade 3 | 37 (0.2) | 60 (0.4) | 97 (0.3) |
| Grade 4 | 0 | 1 (<0.1) | 1 (<0.1) |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=15154) n (%) | mRNA-1273 (N=15167) n (%) | Total (N=30322) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Nausea/Vomiting - N1 | 15149 | 15162 | 30312 |
| Any | 1074 (7.1) | 1263 (8.3) | 2337 (7.7) |
| Grade 1 | 890 (5.9) | 1050 (6.9) | 1940 (6.4) |
| Grade 2 | 172 (1.1) | 203 (1.3) | 375 (1.2) |
| Grade 3 | 12 (<0.1) | 10 (<0.1) | 22 (<0.1) |
| Grade 4 | 0 | 0 | 0 |
| Chills - N1 | 15149 | 15162 | 30312 |
| Any | 878 (5.8) | 1253 (8.3) | 2131 (7.0) |
| Grade 1 | 706 (4.7) | 940 (6.2) | 1646 (5.4) |
| Grade 2 | 158 (1.0) | 289 (1.9) | 447 (1.5) |
| Grade 3 | 14 (<0.1) | 24 (0.2) | 38 (0.1) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=13870) n (%) | mRNA-1273 (N=13947) n (%) | Total (N=27817) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Solicited Adverse Reactions - N1 | 13870 | 13947 | 27817 |
| Any Solicited Adverse Reactions | 5942 (42.8) | 12877 (92.3) | 18819 (67.7) |
| 95% CI | 42.0, 43.7 | 91.9, 92.8 | 67.1, 68.2 |
| Grade 1 | 4168 (30.1) | 4653 (33.4) | 8821 (31.7) |
| Grade 2 | 1440 (10.4) | 5486 (39.3) | 6926 (24.9) |
| Grade 3 | 331 (2.4) | 2726 (19.5) | 3057 (11.0) |
| Grade 4 | 3 (<0.1) | 12 (<0.1) | 15 (<0.1) |
| Solicited Local Adverse Reactions - N1 | 13866 | 13944 | 27810 |
| Any Solicited Local Adverse Reactions | 2607 (18.8) | 12381 (88.8) | 14988 (53.9) |
| 95% CI | 18.2, 19.5 | 88.3, 89.3 | 53.3, 54.5 |
| Grade 1 | 2459 (17.7) | 8375 (60.1) | 10834 (39.0) |
| Grade 2 | 78 (0.6) | 3028 (21.7) | 3106 (11.2) |
| Grade 3 | 70 (0.5) | 978 (7.0) | 1048 (3.8) |
| Grade 4 | 0 | 0 | 0 |
| Pain - N1 | 13866 | 13944 | 27810 |
| Any | 2363 (17.0) | 12325 (88.4) | 14688 (52.8) |
| Grade 1 | 2269 (16.4) | 9064 (65.0) | 11333 (40.8) |
| Grade 2 | 56 (0.4) | 2686 (19.3) | 2742 (9.9) |
| Grade 3 | 38 (0.3) | 575 (4.1) | 613 (2.2) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=13870) n (%) | mRNA-1273 (N=13947) n (%) | Total (N=27817) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Erythema (Redness) - N1 | 13866 | 13944 | 27810 |
| Any | 55 (0.4) | 1193 (8.6) | 1248 (4.5) |
| Grade 1 | 37 (0.3) | 412 (3.0) | 449 (1.6) |
| Grade 2 | 3 (<0.1) | 500 (3.6) | 503 (1.8) |
| Grade 3 | 15 (0.1) | 281 (2.0) | 296 (1.1) |
| Grade 4 | 0 | 0 | 0 |
| Swelling (Hardness) - N1 | 13866 | 13944 | 27810 |
| Any | 48 (0.3) | 1695 (12.2) | 1743 (6.3) |
| Grade 1 | 29 (0.2) | 841 (6.0) | 870 (3.1) |
| Grade 2 | 8 (<0.1) | 609 (4.4) | 617 (2.2) |
| Grade 3 | 11 (<0.1) | 245 (1.8) | 256 (0.9) |
| Grade 4 | 0 | 0 | 0 |
| Lymphadenopathy - N1 [1] | 13866 | 13944 | 27810 |
| Any | 534 (3.9) | 1956 (14.0) | 2490 (9.0) |
| Grade 1 | 490 (3.5) | 1629 (11.7) | 2119 (7.6) |
| Grade 2 | 26 (0.2) | 261 (1.9) | 287 (1.0) |
| Grade 3 | 18 (0.1) | 66 (0.5) | 84 (0.3) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=13870) n (%) | mRNA-1273 (N=13947) n (%) | Total (N=27817) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Solicited Systemic Adverse Reactions - N1 | 13869 | 13947 | 27816 |
| Any Solicited Systemic Adverse Reactions | 5069 (36.5) | 11064 (79.3) | 16133 (58.0) |
| 95% CI | 35.7, 37.4 | 78.6, 80.0 | 57.4, 58.6 |
| Grade 1 | 3373 (24.3) | 3563 (25.5) | 6936 (24.9) |
| Grade 2 | 1420 (10.2) | 5301 (38.0) | 6721 (24.2) |
| Grade 3 | 273 (2.0) | 2188 (15.7) | 2461 (8.8) |
| Grade 4 | 3 (<0.1) | 12 (<0.1) | 15 (<0.1) |
| Fever - N1 | 13864 | 13939 | 27803 |
| Any | 43 (0.3) | 2172 (15.6) | 2215 (8.0) |
| Grade 1 | 34 (0.2) | 1306 (9.4) | 1340 (4.8) |
| Grade 2 | 5 (<0.1) | 669 (4.8) | 674 (2.4) |
| Grade 3 | 1 (<0.1) | 186 (1.3) | 187 (0.7) |
| Grade 4 | 3 (<0.1) | 11 (<0.1) | 14 (<0.1) |
| Headache - N1 | 13866 | 13944 | 27810 |
| Any | 3252 (23.5) | 8165 (58.6) | 11417 (41.1) |
| Grade 1 | 2606 (18.8) | 4589 (32.9) | 7195 (25.9) |
| Grade 2 | 490 (3.5) | 2954 (21.2) | 3444 (12.4) |
| Grade 3 | 156 (1.1) | 622 (4.5) | 778 (2.8) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=13870) n (%) | mRNA-1273 (N=13947) n (%) | Total (N=27817) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Fatigue - N1 | 13864 | 13944 | 27808 |
| Any | 3225 (23.3) | 9096 (65.2) | 12321 (44.3) |
| Grade 1 | 2082 (15.0) | 3280 (23.5) | 5362 (19.3) |
| Grade 2 | 1042 (7.5) | 4469 (32.0) | 5511 (19.8) |
| Grade 3 | 101 (0.7) | 1347 (9.7) | 1448 (5.2) |
| Grade 4 | 0 | 0 | 0 |
| Myalgia - N1 | 13865 | 13944 | 27809 |
| Any | 1697 (12.2) | 8036 (57.6) | 9733 (35.0) |
| Grade 1 | 1221 (8.8) | 3068 (22.0) | 4289 (15.4) |
| Grade 2 | 427 (3.1) | 3735 (26.8) | 4162 (15.0) |
| Grade 3 | 49 (0.4) | 1233 (8.8) | 1282 (4.6) |
| Grade 4 | 0 | 0 | 0 |
| Arthralgia - N1 | 13864 | 13944 | 27808 |
| Any | 1468 (10.6) | 5937 (42.6) | 7405 (26.6) |
| Grade 1 | 1069 (7.7) | 2656 (19.0) | 3725 (13.4) |
| Grade 2 | 356 (2.6) | 2556 (18.3) | 2912 (10.5) |
| Grade 3 | 43 (0.3) | 725 (5.2) | 768 (2.8) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=13870) n (%) | mRNA-1273 (N=13947) n (%) | Total (N=27817) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Nausea/Vomiting - N1 | 13864 | 13944 | 27808 |
| Any | 883 (6.4) | 2634 (18.9) | 3517 (12.6) |
| Grade 1 | 715 (5.2) | 1978 (14.2) | 2693 (9.7) |
| Grade 2 | 157 (1.1) | 637 (4.6) | 794 (2.9) |
| Grade 3 | 11 (<0.1) | 18 (0.1) | 29 (0.1) |
| Grade 4 | 0 | 1 (<0.1) | 1 (<0.1) |
| Chills - N1 | 13864 | 13944 | 27808 |
| Any | 755 (5.4) | 6100 (43.7) | 6855 (24.7) |
| Grade 1 | 583 (4.2) | 2737 (19.6) | 3320 (11.9) |
| Grade 2 | 156 (1.1) | 3185 (22.8) | 3341 (12.0) |
| Grade 3 | 16 (0.1) | 178 (1.3) | 194 (0.7) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=11406) n (%) | mRNA-1273 (N=11405) n (%) | Total (N=22812) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Solicited Adverse Reactions - N1 | 11406 | 11405 | 22812 |
| Any Solicited Adverse Reactions | 5736 (50.3) | 10262 (90.0) | 15998 (70.1) |
| 95% CI | 49.4, 51.2 | 89.4, 90.5 | 69.5, 70.7 |
| Grade 1 | 4000 (35.1) | 6956 (61.0) | 10956 (48.0) |
| Grade 2 | 1460 (12.8) | 2597 (22.8) | 4057 (17.8) |
| Grade 3 | 272 (2.4) | 704 (6.2) | 976 (4.3) |
| Grade 4 | 4 (<0.1) | 5 (<0.1) | 9 (<0.1) |
| Solicited Local Adverse Reactions - N1 | 11404 | 11401 | 22806 |
| Any Solicited Local Adverse Reactions | 2432 (21.3) | 9960 (87.4) | 12392 (54.3) |
| 95% CI | 20.6, 22.1 | 86.7, 88.0 | 53.7, 55.0 |
| Grade 1 | 2336 (20.5) | 8151 (71.5) | 10487 (46.0) |
| Grade 2 | 57 (0.5) | 1357 (11.9) | 1414 (6.2) |
| Grade 3 | 39 (0.3) | 452 (4.0) | 491 (2.2) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=11406) n (%) | mRNA-1273 (N=11405) n (%) | Total (N=22812) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Pain - N1 | 11404 | 11401 | 22806 |
| Any | 2179 (19.1) | 9908 (86.9) | 12087 (53.0) |
| Grade 1 | 2117 (18.6) | 8359 (73.3) | 10476 (45.9) |
| Grade 2 | 39 (0.3) | 1182 (10.4) | 1221 (5.4) |
| Grade 3 | 23 (0.2) | 367 (3.2) | 390 (1.7) |
| Grade 4 | 0 | 0 | 0 |
| Erythema (Redness) - N1 | 11404 | 11401 | 22806 |
| Any | 46 (0.4) | 345 (3.0) | 391 (1.7) |
| Grade 1 | 31 (0.3) | 213 (1.9) | 244 (1.1) |
| Grade 2 | 4 (<0.1) | 98 (0.9) | 102 (0.4) |
| Grade 3 | 11 (<0.1) | 34 (0.3) | 45 (0.2) |
| Grade 4 | 0 | 0 | 0 |
| Swelling (Hardness) - N1 | 11404 | 11401 | 22806 |
| Any | 33 (0.3) | 768 (6.7) | 801 (3.5) |
| Grade 1 | 27 (0.2) | 502 (4.4) | 529 (2.3) |
| Grade 2 | 3 (<0.1) | 204 (1.8) | 207 (0.9) |
| Grade 3 | 3 (<0.1) | 62 (0.5) | 65 (0.3) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=11406) n (%) | mRNA-1273 (N=11405) n (%) | Total (N=22812) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Lymphadenopathy - N1 [1] | 11404 | 11401 | 22806 |
| Any | 567 (5.0) | 1322 (11.6) | 1889 (8.3) |
| Grade 1 | 535 (4.7) | 1181 (10.4) | 1716 (7.5) |
| Grade 2 | 19 (0.2) | 105 (0.9) | 124 (0.5) |
| Grade 3 | 13 (0.1) | 36 (0.3) | 49 (0.2) |
| Grade 4 | 0 | 0 | 0 |
| Solicited Systemic Adverse Reactions - N1 | 11406 | 11405 | 22812 |
| Any Solicited Systemic Adverse Reactions | 5063 (44.4) | 6503 (57.0) | 11566 (50.7) |
| 95% CI | 43.5, 45.3 | 56.1, 57.9 | 50.1, 51.4 |
| Grade 1 | 3372 (29.6) | 4089 (35.9) | 7461 (32.7) |
| Grade 2 | 1439 (12.6) | 2046 (17.9) | 3485 (15.3) |
| Grade 3 | 248 (2.2) | 363 (3.2) | 611 (2.7) |
| Grade 4 | 4 (<0.1) | 5 (<0.1) | 9 (<0.1) |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=11406) n (%) | mRNA-1273 (N=11405) n (%) | Total (N=22812) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Fever - N1 | 11404 | 11403 | 22808 |
| Any | 39 (0.3) | 105 (0.9) | 144 (0.6) |
| Grade 1 | 28 (0.2) | 67 (0.6) | 95 (0.4) |
| Grade 2 | 6 (<0.1) | 24 (0.2) | 30 (0.1) |
| Grade 3 | 1 (<0.1) | 10 (<0.1) | 11 (<0.1) |
| Grade 4 | 4 (<0.1) | 4 (<0.1) | 8 (<0.1) |
| Headache - N1 | 11404 | 11401 | 22806 |
| Any | 3303 (29.0) | 4031 (35.4) | 7334 (32.2) |
| Grade 1 | 2673 (23.4) | 3174 (27.8) | 5847 (25.6) |
| Grade 2 | 468 (4.1) | 638 (5.6) | 1106 (4.8) |
| Grade 3 | 162 (1.4) | 219 (1.9) | 381 (1.7) |
| Grade 4 | 0 | 0 | 0 |
| Fatigue - N1 | 11404 | 11401 | 22806 |
| Any | 3282 (28.8) | 4384 (38.5) | 7666 (33.6) |
| Grade 1 | 2103 (18.4) | 2743 (24.1) | 4846 (21.2) |
| Grade 2 | 1096 (9.6) | 1520 (13.3) | 2616 (11.5) |
| Grade 3 | 83 (0.7) | 120 (1.1) | 203 (0.9) |
| Grade 4 | 0 | 1 (<0.1) | 1 (<0.1) |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=11406) n (%) | mRNA-1273 (N=11405) n (%) | Total (N=22812) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Myalgia - N1 | 11404 | 11401 | 22806 |
| Any | 1626 (14.3) | 2698 (23.7) | 4324 (19.0) |
| Grade 1 | 1204 (10.6) | 1875 (16.4) | 3079 (13.5) |
| Grade 2 | 384 (3.4) | 750 (6.6) | 1134 (5.0) |
| Grade 3 | 38 (0.3) | 73 (0.6) | 111 (0.5) |
| Grade 4 | 0 | 0 | 0 |
| Arthralgia - N1 | 11404 | 11401 | 22806 |
| Any | 1327 (11.6) | 1892 (16.6) | 3219 (14.1) |
| Grade 1 | 970 (8.5) | 1369 (12.0) | 2339 (10.3) |
| Grade 2 | 328 (2.9) | 475 (4.2) | 803 (3.5) |
| Grade 3 | 29 (0.3) | 47 (0.4) | 76 (0.3) |
| Grade 4 | 0 | 1 (<0.1) | 1 (<0.1) |
| Nausea/Vomiting - N1 | 11404 | 11401 | 22806 |
| Any | 908 (8.0) | 1069 (9.4) | 1977 (8.7) |
| Grade 1 | 752 (6.6) | 891 (7.8) | 1643 (7.2) |
| Grade 2 | 148 (1.3) | 172 (1.5) | 320 (1.4) |
| Grade 3 | 8 (<0.1) | 6 (<0.1) | 14 (<0.1) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=11406) n (%) | mRNA-1273 (N=11405) n (%) | Total (N=22812) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Chills - N1 | 11404 | 11401 | 22806 |
| Any | 730 (6.4) | 1051 (9.2) | 1781 (7.8) |
| Grade 1 | 584 (5.1) | 781 (6.9) | 1365 (6.0) |
| Grade 2 | 138 (1.2) | 253 (2.2) | 391 (1.7) |
| Grade 3 | 8 (<0.1) | 17 (0.1) | 25 (0.1) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=3748) n (%) | mRNA-1273 (N=3762) n (%) | Total (N=7510) n (%) |
|---|------------------------------|--------------------------------|----------------------------|
| Solicited Adverse Reactions - N1 | 3748 | 3762 | 7510 |
| Any Solicited Adverse Reactions | 1546 (41.2) | 3058 (81.3) | 4604 (61.3) |
| 95% CI | 39.7, 42.8 | 80.0, 82.5 | 60.2, 62.4 |
| Grade 1 | 1145 (30.5) | 2383 (63.3) | 3528 (47.0) |
| Grade 2 | 309 (8.2) | 531 (14.1) | 840 (11.2) |
| Grade 3 | 90 (2.4) | 144 (3.8) | 234 (3.1) |
| Grade 4 | 2 (<0.1) | 0 | 2 (<0.1) |
| Solicited Local Adverse Reactions - N1 | 3746 | 3762 | 7508 |
| Any Solicited Local Adverse Reactions | 566 (15.1) | 2805 (74.6) | 3371 (44.9) |
| 95% CI | 14.0, 16.3 | 73.1, 75.9 | 43.8, 46.0 |
| Grade 1 | 503 (13.4) | 2577 (68.5) | 3080 (41.0) |
| Grade 2 | 24 (0.6) | 151 (4.0) | 175 (2.3) |
| Grade 3 | 39 (1.0) | 77 (2.0) | 116 (1.5) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=3748) n (%) | mRNA-1273 (N=3762) n (%) | Total (N=7510) n (%) |
|---|---------------------------|-----------------------------|-------------------------|
| Pain - N1 | 3746 | 3762 | 7508 |
| Any | 481 (12.8) | 2782 (74.0) | 3263 (43.5) |
| Grade 1 | 435 (11.6) | 2628 (69.9) | 3063 (40.8) |
| Grade 2 | 14 (0.4) | 104 (2.8) | 118 (1.6) |
| Grade 3 | 32 (0.9) | 50 (1.3) | 82 (1.1) |
| Grade 4 | 0 | 0 | 0 |
| Erythema (Redness) - N1 | 3746 | 3761 | 7507 |
| Any | 19 (0.5) | 86 (2.3) | 105 (1.4) |
| Grade 1 | 14 (0.4) | 55 (1.5) | 69 (0.9) |
| Grade 2 | 3 (<0.1) | 23 (0.6) | 26 (0.3) |
| Grade 3 | 2 (<0.1) | 8 (0.2) | 10 (0.1) |
| Grade 4 | 0 | 0 | 0 |
| Swelling (Hardness) - N1 | 3746 | 3761 | 7507 |
| Any | 19 (0.5) | 166 (4.4) | 185 (2.5) |
| Grade 1 | 12 (0.3) | 106 (2.8) | 118 (1.6) |
| Grade 2 | 4 (0.1) | 40 (1.1) | 44 (0.6) |
| Grade 3 | 3 (<0.1) | 20 (0.5) | 23 (0.3) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=3748) n (%) | mRNA-1273 (N=3762) n (%) | Total (N=7510) n (%) |
|---|------------------------------|--------------------------------|----------------------------|
| Lymphadenopathy - N1 [1] | 3746 | 3761 | 7507 |
| Any | 155 (4.1) | 231 (6.1) | 386 (5.1) |
| Grade 1 | 134 (3.6) | 214 (5.7) | 348 (4.6) |
| Grade 2 | 7 (0.2) | 5 (0.1) | 12 (0.2) |
| Grade 3 | 14 (0.4) | 12 (0.3) | 26 (0.3) |
| Grade 4 | 0 | 0 | 0 |
| Solicited Systemic Adverse Reactions - N1 | 3748 | 3761 | 7509 |
| Any Solicited Systemic Adverse Reactions | 1335 (35.6) | 1818 (48.3) | 3153 (42.0) |
| 95% CI | 34.1, 37.2 | 46.7, 49.9 | 40.9, 43.1 |
| Grade 1 | 973 (26.0) | 1281 (34.1) | 2254 (30.0) |
| Grade 2 | 299 (8.0) | 453 (12.0) | 752 (10.0) |
| Grade 3 | 61 (1.6) | 84 (2.2) | 145 (1.9) |
| Grade 4 | 2 (<0.1) | 0 | 2 (<0.1) |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=3748) n (%) | mRNA-1273 (N=3762) n (%) | Total (N=7510) n (%) |
|---|------------------------------|--------------------------------|----------------------------|
| Fever - N1 | 3748 | 3760 | 7508 |
| Any | 7 (0.2) | 10 (0.3) | 17 (0.2) |
| Grade 1 | 3 (<0.1) | 7 (0.2) | 10 (0.1) |
| Grade 2 | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Grade 3 | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Grade 4 | 2 (<0.1) | 0 | 2 (<0.1) |
| Headache - N1 | 3745 | 3761 | 7506 |
| Any | 724 (19.3) | 921 (24.5) | 1645 (21.9) |
| Grade 1 | 631 (16.8) | 779 (20.7) | 1410 (18.8) |
| Grade 2 | 59 (1.6) | 90 (2.4) | 149 (2.0) |
| Grade 3 | 34 (0.9) | 52 (1.4) | 86 (1.1) |
| Grade 4 | 0 | 0 | 0 |
| Fatigue - N1 | 3745 | 3761 | 7506 |
| Any | 851 (22.7) | 1251 (33.3) | 2102 (28.0) |
| Grade 1 | 605 (16.2) | 856 (22.8) | 1461 (19.5) |
| Grade 2 | 223 (6.0) | 365 (9.7) | 588 (7.8) |
| Grade 3 | 23 (0.6) | 30 (0.8) | 53 (0.7) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=3748) n (%) | mRNA-1273 (N=3762) n (%) | Total (N=7510) n (%) |
|---|---------------------------|-----------------------------|-------------------------|
| Myalgia - N1 | 3745 | 3761 | 7506 |
| Any | 443 (11.8) | 743 (19.8) | 1186 (15.8) |
| Grade 1 | 362 (9.7) | 569 (15.1) | 931 (12.4) |
| Grade 2 | 72 (1.9) | 157 (4.2) | 229 (3.1) |
| Grade 3 | 9 (0.2) | 17 (0.5) | 26 (0.3) |
| Grade 4 | 0 | 0 | 0 |
| Arthralgia - N1 | 3745 | 3761 | 7506 |
| Any | 456 (12.2) | 618 (16.4) | 1074 (14.3) |
| Grade 1 | 372 (9.9) | 475 (12.6) | 847 (11.3) |
| Grade 2 | 76 (2.0) | 130 (3.5) | 206 (2.7) |
| Grade 3 | 8 (0.2) | 13 (0.3) | 21 (0.3) |
| Grade 4 | 0 | 0 | 0 |
| Nausea/Vomiting - N1 | 3745 | 3761 | 7506 |
| Any | 166 (4.4) | 194 (5.2) | 360 (4.8) |
| Grade 1 | 138 (3.7) | 159 (4.2) | 297 (4.0) |
| Grade 2 | 24 (0.6) | 31 (0.8) | 55 (0.7) |
| Grade 3 | 4 (0.1) | 4 (0.1) | 8 (0.1) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.4
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=3748) n (%) | mRNA-1273 (N=3762) n (%) | Total (N=7510) n (%) |
|---|------------------------------|--------------------------------|----------------------------|
| Chills - N1 | 3745 | 3761 | 7506 |
| Any | 148 (4.0) | 202 (5.4) | 350 (4.7) |
| Grade 1 | 122 (3.3) | 159 (4.2) | 281 (3.7) |
| Grade 2 | 20 (0.5) | 36 (1.0) | 56 (0.7) |
| Grade 3 | 6 (0.2) | 7 (0.2) | 13 (0.2) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=10321) n (%) | mRNA-1273 (N=10358) n (%) | Total (N=20679) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Solicited Adverse Reactions - N1 | 10321 | 10358 | 20679 |
| Any Solicited Adverse Reactions | 4648 (45.0) | 9664 (93.3) | 14312 (69.2) |
| 95% CI | 44.1, 46.0 | 92.8, 93.8 | 68.6, 69.8 |
| Grade 1 | 3235 (31.3) | 3133 (30.2) | 6368 (30.8) |
| Grade 2 | 1164 (11.3) | 4315 (41.7) | 5479 (26.5) |
| Grade 3 | 247 (2.4) | 2206 (21.3) | 2453 (11.9) |
| Grade 4 | 2 (<0.1) | 10 (<0.1) | 12 (<0.1) |
| Solicited Local Adverse Reactions - N1 | 10317 | 10357 | 20674 |
| Any Solicited Local Adverse Reactions | 2134 (20.7) | 9371 (90.5) | 11505 (55.6) |
| 95% CI | 19.9, 21.5 | 89.9, 91.0 | 55.0, 56.3 |
| Grade 1 | 2029 (19.7) | 6063 (58.5) | 8092 (39.1) |
| Grade 2 | 64 (0.6) | 2542 (24.5) | 2606 (12.6) |
| Grade 3 | 41 (0.4) | 766 (7.4) | 807 (3.9) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=10321) n (%) | mRNA-1273 (N=10358) n (%) | Total (N=20679) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Pain - N1 | 10317 | 10357 | 20674 |
| Any | 1942 (18.8) | 9335 (90.1) | 11277 (54.5) |
| Grade 1 | 1878 (18.2) | 6553 (63.3) | 8431 (40.8) |
| Grade 2 | 43 (0.4) | 2303 (22.2) | 2346 (11.3) |
| Grade 3 | 21 (0.2) | 479 (4.6) | 500 (2.4) |
| Grade 4 | 0 | 0 | 0 |
| Erythema (Redness) - N1 | 10317 | 10357 | 20674 |
| Any | 42 (0.4) | 928 (9.0) | 970 (4.7) |
| Grade 1 | 27 (0.3) | 324 (3.1) | 351 (1.7) |
| Grade 2 | 3 (<0.1) | 398 (3.8) | 401 (1.9) |
| Grade 3 | 12 (0.1) | 206 (2.0) | 218 (1.1) |
| Grade 4 | 0 | 0 | 0 |
| Swelling (Hardness) - N1 | 10317 | 10357 | 20674 |
| Any | 35 (0.3) | 1309 (12.6) | 1344 (6.5) |
| Grade 1 | 24 (0.2) | 656 (6.3) | 680 (3.3) |
| Grade 2 | 7 (<0.1) | 477 (4.6) | 484 (2.3) |
| Grade 3 | 4 (<0.1) | 176 (1.7) | 180 (0.9) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=10321) n (%) | mRNA-1273 (N=10358) n (%) | Total (N=20679) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Lymphadenopathy - N1 [1] | 10317 | 10357 | 20674 |
| Any | 444 (4.3) | 1654 (16.0) | 2098 (10.1) |
| Grade 1 | 408 (4.0) | 1373 (13.3) | 1781 (8.6) |
| Grade 2 | 26 (0.3) | 236 (2.3) | 262 (1.3) |
| Grade 3 | 10 (<0.1) | 45 (0.4) | 55 (0.3) |
| Grade 4 | 0 | 0 | 0 |
| Solicited Systemic Adverse Reactions - N1 | 10320 | 10358 | 20678 |
| Any Solicited Systemic Adverse Reactions | 3967 (38.4) | 8484 (81.9) | 12451 (60.2) |
| 95% CI | 37.5, 39.4 | 81.2, 82.6 | 59.5, 60.9 |
| Grade 1 | 2599 (25.2) | 2489 (24.0) | 5088 (24.6) |
| Grade 2 | 1151 (11.2) | 4184 (40.4) | 5335 (25.8) |
| Grade 3 | 215 (2.1) | 1801 (17.4) | 2016 (9.7) |
| Grade 4 | 2 (<0.1) | 10 (<0.1) | 12 (<0.1) |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=10321) n (%) | mRNA-1273 (N=10358) n (%) | Total (N=20679) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Fever - N1 | 10315 | 10352 | 20667 |
| Any | 38 (0.4) | 1806 (17.4) | 1844 (8.9) |
| Grade 1 | 31 (0.3) | 1052 (10.2) | 1083 (5.2) |
| Grade 2 | 4 (<0.1) | 576 (5.6) | 580 (2.8) |
| Grade 3 | 1 (<0.1) | 168 (1.6) | 169 (0.8) |
| Grade 4 | 2 (<0.1) | 10 (<0.1) | 12 (<0.1) |
| Headache - N1 | 10317 | 10357 | 20674 |
| Any | 2617 (25.4) | 6500 (62.8) | 9117 (44.1) |
| Grade 1 | 2061 (20.0) | 3468 (33.5) | 5529 (26.7) |
| Grade 2 | 432 (4.2) | 2517 (24.3) | 2949 (14.3) |
| Grade 3 | 124 (1.2) | 515 (5.0) | 639 (3.1) |
| Grade 4 | 0 | 0 | 0 |
| Fatigue - N1 | 10315 | 10357 | 20672 |
| Any | 2530 (24.5) | 7002 (67.6) | 9532 (46.1) |
| Grade 1 | 1612 (15.6) | 2399 (23.2) | 4011 (19.4) |
| Grade 2 | 837 (8.1) | 3504 (33.8) | 4341 (21.0) |
| Grade 3 | 81 (0.8) | 1099 (10.6) | 1180 (5.7) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=10321) n (%) | mRNA-1273 (N=10358) n (%) | Total (N=20679) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Myalgia - N1 | 10316 | 10357 | 20673 |
| Any | 1312 (12.7) | 6353 (61.3) | 7665 (37.1) |
| Grade 1 | 926 (9.0) | 2271 (21.9) | 3197 (15.5) |
| Grade 2 | 347 (3.4) | 3050 (29.4) | 3397 (16.4) |
| Grade 3 | 39 (0.4) | 1032 (10.0) | 1071 (5.2) |
| Grade 4 | 0 | 0 | 0 |
| Arthralgia - N1 | 10315 | 10357 | 20672 |
| Any | 1087 (10.5) | 4685 (45.2) | 5772 (27.9) |
| Grade 1 | 775 (7.5) | 1974 (19.1) | 2749 (13.3) |
| Grade 2 | 276 (2.7) | 2108 (20.4) | 2384 (11.5) |
| Grade 3 | 36 (0.3) | 603 (5.8) | 639 (3.1) |
| Grade 4 | 0 | 0 | 0 |
| Nausea/Vomiting - N1 | 10315 | 10357 | 20672 |
| Any | 754 (7.3) | 2209 (21.3) | 2963 (14.3) |
| Grade 1 | 609 (5.9) | 1649 (15.9) | 2258 (10.9) |
| Grade 2 | 137 (1.3) | 552 (5.3) | 689 (3.3) |
| Grade 3 | 8 (<0.1) | 8 (<0.1) | 16 (<0.1) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=10321) n (%) | mRNA-1273 (N=10358) n (%) | Total (N=20679) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Chills - N1 | 10315 | 10357 | 20672 |
| Any | 611 (5.9) | 5001 (48.3) | 5612 (27.1) |
| Grade 1 | 465 (4.5) | 2167 (20.9) | 2632 (12.7) |
| Grade 2 | 132 (1.3) | 2683 (25.9) | 2815 (13.6) |
| Grade 3 | 14 (0.1) | 151 (1.5) | 165 (0.8) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=3549) n (%) | mRNA-1273 (N=3589) n (%) | Total (N=7138) n (%) |
|---|------------------------------|--------------------------------|----------------------------|
| Solicited Adverse Reactions - N1 | 3549 | 3589 | 7138 |
| Any Solicited Adverse Reactions | 1294 (36.5) | 3213 (89.5) | 4507 (63.1) |
| 95% CI | 34.9, 38.1 | 88.5, 90.5 | 62.0, 64.3 |
| Grade 1 | 933 (26.3) | 1520 (42.4) | 2453 (34.4) |
| Grade 2 | 276 (7.8) | 1171 (32.6) | 1447 (20.3) |
| Grade 3 | 84 (2.4) | 520 (14.5) | 604 (8.5) |
| Grade 4 | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Solicited Local Adverse Reactions - N1 | 3549 | 3587 | 7136 |
| Any Solicited Local Adverse Reactions | 473 (13.3) | 3010 (83.9) | 3483 (48.8) |
| 95% CI | 12.2, 14.5 | 82.7, 85.1 | 47.6, 50.0 |
| Grade 1 | 430 (12.1) | 2312 (64.5) | 2742 (38.4) |
| Grade 2 | 14 (0.4) | 486 (13.5) | 500 (7.0) |
| Grade 3 | 29 (0.8) | 212 (5.9) | 241 (3.4) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=3549) n (%) | mRNA-1273 (N=3589) n (%) | Total (N=7138) n (%) |
|---|------------------------------|--------------------------------|----------------------------|
| Pain - N1 | 3549 | 3587 | 7136 |
| Any | 421 (11.9) | 2990 (83.4) | 3411 (47.8) |
| Grade 1 | 391 (11.0) | 2511 (70.0) | 2902 (40.7) |
| Grade 2 | 13 (0.4) | 383 (10.7) | 396 (5.5) |
| Grade 3 | 17 (0.5) | 96 (2.7) | 113 (1.6) |
| Grade 4 | 0 | 0 | 0 |
| Erythema (Redness) - N1 | 3549 | 3587 | 7136 |
| Any | 13 (0.4) | 265 (7.4) | 278 (3.9) |
| Grade 1 | 10 (0.3) | 88 (2.5) | 98 (1.4) |
| Grade 2 | 0 | 102 (2.8) | 102 (1.4) |
| Grade 3 | 3 (<0.1) | 75 (2.1) | 78 (1.1) |
| Grade 4 | 0 | 0 | 0 |
| Swelling (Hardness) - N1 | 3549 | 3587 | 7136 |
| Any | 13 (0.4) | 386 (10.8) | 399 (5.6) |
| Grade 1 | 5 (0.1) | 185 (5.2) | 190 (2.7) |
| Grade 2 | 1 (<0.1) | 132 (3.7) | 133 (1.9) |
| Grade 3 | 7 (0.2) | 69 (1.9) | 76 (1.1) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=3549) n (%) | mRNA-1273 (N=3589) n (%) | Total (N=7138) n (%) |
|---|------------------------------|--------------------------------|----------------------------|
| Lymphadenopathy - N1 [1] | 3549 | 3587 | 7136 |
| Any | 90 (2.5) | 302 (8.4) | 392 (5.5) |
| Grade 1 | 82 (2.3) | 256 (7.1) | 338 (4.7) |
| Grade 2 | 0 | 25 (0.7) | 25 (0.4) |
| Grade 3 | 8 (0.2) | 21 (0.6) | 29 (0.4) |
| Grade 4 | 0 | 0 | 0 |
| Solicited Systemic Adverse Reactions - N1 | 3549 | 3589 | 7138 |
| Any Solicited Systemic Adverse Reactions | 1102 (31.1) | 2580 (71.9) | 3682 (51.6) |
| 95% CI | 29.5, 32.6 | 70.4, 73.4 | 50.4, 52.7 |
| Grade 1 | 774 (21.8) | 1074 (29.9) | 1848 (25.9) |
| Grade 2 | 269 (7.6) | 1117 (31.1) | 1386 (19.4) |
| Grade 3 | 58 (1.6) | 387 (10.8) | 445 (6.2) |
| Grade 4 | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=3549) n (%) | mRNA-1273 (N=3589) n (%) | Total (N=7138) n (%) |
|---|------------------------------|--------------------------------|----------------------------|
| Fever - N1 | 3549 | 3587 | 7136 |
| Any | 5 (0.1) | 366 (10.2) | 371 (5.2) |
| Grade 1 | 3 (<0.1) | 254 (7.1) | 257 (3.6) |
| Grade 2 | 1 (<0.1) | 93 (2.6) | 94 (1.3) |
| Grade 3 | 0 | 18 (0.5) | 18 (0.3) |
| Grade 4 | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Headache - N1 | 3549 | 3587 | 7136 |
| Any | 635 (17.9) | 1665 (46.4) | 2300 (32.2) |
| Grade 1 | 545 (15.4) | 1121 (31.3) | 1666 (23.3) |
| Grade 2 | 58 (1.6) | 437 (12.2) | 495 (6.9) |
| Grade 3 | 32 (0.9) | 107 (3.0) | 139 (1.9) |
| Grade 4 | 0 | 0 | 0 |
| Fatigue - N1 | 3549 | 3587 | 7136 |
| Any | 695 (19.6) | 2094 (58.4) | 2789 (39.1) |
| Grade 1 | 470 (13.2) | 881 (24.6) | 1351 (18.9) |
| Grade 2 | 205 (5.8) | 965 (26.9) | 1170 (16.4) |
| Grade 3 | 20 (0.6) | 248 (6.9) | 268 (3.8) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=3549) n (%) | mRNA-1273 (N=3589) n (%) | Total (N=7138) n (%) |
|---|------------------------------|--------------------------------|----------------------------|
| Myalgia - N1 | 3549 | 3587 | 7136 |
| Any | 385 (10.8) | 1683 (46.9) | 2068 (29.0) |
| Grade 1 | 295 (8.3) | 797 (22.2) | 1092 (15.3) |
| Grade 2 | 80 (2.3) | 685 (19.1) | 765 (10.7) |
| Grade 3 | 10 (0.3) | 201 (5.6) | 211 (3.0) |
| Grade 4 | 0 | 0 | 0 |
| Arthralgia - N1 | 3549 | 3587 | 7136 |
| Any | 381 (10.7) | 1252 (34.9) | 1633 (22.9) |
| Grade 1 | 294 (8.3) | 682 (19.0) | 976 (13.7) |
| Grade 2 | 80 (2.3) | 448 (12.5) | 528 (7.4) |
| Grade 3 | 7 (0.2) | 122 (3.4) | 129 (1.8) |
| Grade 4 | 0 | 0 | 0 |
| Nausea/Vomiting - N1 | 3549 | 3587 | 7136 |
| Any | 129 (3.6) | 425 (11.8) | 554 (7.8) |
| Grade 1 | 106 (3.0) | 329 (9.2) | 435 (6.1) |
| Grade 2 | 20 (0.6) | 85 (2.4) | 105 (1.5) |
| Grade 3 | 3 (<0.1) | 10 (0.3) | 13 (0.2) |
| Grade 4 | 0 | 1 (<0.1) | 1 (<0.1) |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.5
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

| Solicited Adverse Reaction Category Grade | Placebo (N=3549) n (%) | mRNA-1273 (N=3589) n (%) | Total (N=7138) n (%) |
|---|------------------------------|--------------------------------|----------------------------|
| Chills - N1 | 3549 | 3587 | 7136 |
| Any | 144 (4.1) | 1099 (30.6) | 1243 (17.4) |
| Grade 1 | 118 (3.3) | 570 (15.9) | 688 (9.6) |
| Grade 2 | 24 (0.7) | 502 (14.0) | 526 (7.4) |
| Grade 3 | 2 (<0.1) | 27 (0.8) | 29 (0.4) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

| Solicited Adverse Reaction Category Statistic | Placebo (N=15154) | mRNA-1273 (N=15167) | Total (N=30322) |
|---|----------------------|------------------------|--------------------|
| Solicited Adverse Reactions | | | |
| n | 7282 | 13320 | 20602 |
| Mean (SD) | 3.1 (3.92) | 3.4 (3.17) | 3.3 (3.46) |
| Median | 2.0 | 3.0 | 3.0 |
| Min, Max | 1, 74 | 1, 70 | 1, 74 |
| Solicited Local Adverse Reactions | | | |
| n | 2998 | 12765 | 15763 |
| Mean (SD) | 1.9 (2.47) | 2.6 (1.89) | 2.5 (2.03) |
| Median | 1.0 | 2.0 | 2.0 |
| Min, Max | 1, 51 | 1, 36 | 1, 51 |
| Pain | | | |
| n | 2660 | 12690 | 15350 |
| Mean (SD) | 1.7 (2.05) | 2.4 (1.44) | 2.3 (1.59) |
| Median | 1.0 | 2.0 | 2.0 |
| Min, Max | 1, 51 | 1, 35 | 1, 51 |
| Erythema (Redness) | | | |
| n | 65 | 431 | 496 |
| Mean (SD) | 2.1 (3.70) | 2.4 (3.18) | 2.3 (3.25) |
| Median | 1.0 | 2.0 | 1.0 |
| Min, Max | 1, 26 | 1, 35 | 1, 35 |

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

| Solicited Adverse Reaction Category Statistic | Placebo (N=15154) | mRNA-1273 (N=15167) | Total (N=30322) |
|---|----------------------|------------------------|--------------------|
| Swelling (Hardness) | | | |
| n | 52 | 934 | 986 |
| Mean (SD) | 4.3 (7.06) | 2.0 (2.01) | 2.1 (2.58) |
| Median | 1.5 | 1.0 | 1.0 |
| Min, Max | 1, 27 | 1, 25 | 1, 27 |
| Lymphadenopathy [1] | | | |
| n | 722 | 1553 | 2275 |
| Mean (SD) | 2.1 (2.74) | 2.3 (2.83) | 2.2 (2.80) |
| Median | 1.0 | 1.0 | 1.0 |
| Min, Max | 1, 33 | 1, 31 | 1, 33 |
| Solicited Systemic Adverse Reactions | | | |
| n | 6398 | 8321 | 14719 |
| Mean (SD) | 3.1 (3.94) | 2.9 (3.54) | 3.0 (3.72) |
| Median | 2.0 | 2.0 | 2.0 |
| Min, Max | 1, 74 | 1, 69 | 1, 74 |
| Fever | | | |
| n | 46 | 115 | 161 |
| Mean (SD) | 1.4 (0.61) | 1.3 (0.70) | 1.3 (0.68) |
| Median | 1.0 | 1.0 | 1.0 |
| Min, Max | 1, 3 | 1, 6 | 1, 6 |

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

| Solicited Adverse Reaction Category Statistic | Placebo (N=15154) | mRNA-1273 (N=15167) | Total (N=30322) |
|---|----------------------|------------------------|--------------------|
| Headache | | | |
| n | 4027 | 4952 | 8979 |
| Mean (SD) | 2.1 (2.35) | 2.1 (2.18) | 2.1 (2.26) |
| Median | 1.0 | 1.0 | 1.0 |
| Min, Max | 1, 33 | 1, 42 | 1, 42 |
| Fatigue | | | |
| n | 4133 | 5635 | 9768 |
| Mean (SD) | 2.8 (3.66) | 2.7 (3.44) | 2.7 (3.54) |
| Median | 2.0 | 2.0 | 2.0 |
| Min, Max | 1, 74 | 1, 69 | 1, 74 |
| Myalgia | | | |
| n | 2069 | 3441 | 5510 |
| Mean (SD) | 2.7 (3.73) | 2.3 (3.01) | 2.4 (3.31) |
| Median | 1.0 | 1.0 | 1.0 |
| Min, Max | 1, 44 | 1, 59 | 1, 59 |
| Arthralgia | | | |
| n | 1783 | 2510 | 4293 |
| Mean (SD) | 3.1 (4.47) | 2.6 (3.82) | 2.8 (4.11) |
| Median | 2.0 | 1.0 | 1.0 |
| Min, Max | 1, 59 | 1, 59 | 1, 59 |

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

| Solicited Adverse Reaction Category Statistic | Placebo (N=15154) | mRNA-1273 (N=15167) | Total (N=30322) |
|---|----------------------|------------------------|--------------------|
| Nausea/Vomiting | | | |
| n | 1074 | 1263 | 2337 |
| Mean (SD) | 1.8 (2.17) | 1.7 (1.59) | 1.7 (1.88) |
| Median | 1.0 | 1.0 | 1.0 |
| Min, Max | 1, 33 | 1, 25 | 1, 33 |
| Chills | | | |
| n | 878 | 1253 | 2131 |
| Mean (SD) | 1.7 (1.71) | 1.5 (1.69) | 1.6 (1.70) |
| Median | 1.0 | 1.0 | 1.0 |
| Min, Max | 1, 33 | 1, 28 | 1, 33 |

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

| Solicited Adverse Reaction Category Statistic | Placebo (N=13870) | mRNA-1273 (N=13947) | Total (N=27817) |
|---|----------------------|------------------------|--------------------|
| Solicited Adverse Reactions | | | |
| n | 5942 | 12877 | 18819 |
| Mean (SD) | 3.3 (4.81) | 4.0 (4.15) | 3.7 (4.38) |
| Median | 2.0 | 3.0 | 3.0 |
| Min, Max | 1, 76 | 1, 72 | 1, 76 |
| Solicited Local Adverse Reactions | | | |
| n | 2607 | 12381 | 14988 |
| Mean (SD) | 2.0 (3.32) | 3.2 (2.55) | 3.0 (2.73) |
| Median | 1.0 | 3.0 | 3.0 |
| Min, Max | 1, 76 | 1, 64 | 1, 76 |
| Pain | | | |
| n | 2363 | 12325 | 14688 |
| Mean (SD) | 1.8 (2.71) | 3.0 (1.99) | 2.8 (2.17) |
| Median | 1.0 | 3.0 | 3.0 |
| Min, Max | 1, 58 | 1, 64 | 1, 64 |
| Erythema (Redness) | | | |
| n | 55 | 1193 | 1248 |
| Mean (SD) | 2.4 (5.16) | 2.6 (3.30) | 2.6 (3.40) |
| Median | 1.0 | 2.0 | 2.0 |
| Min, Max | 1, 38 | 1, 57 | 1, 57 |

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

| Solicited Adverse Reaction Category Statistic | Placebo (N=13870) | mRNA-1273 (N=13947) | Total (N=27817) |
|---|----------------------|------------------------|--------------------|
| Swelling (Hardness) | | | |
| n | 48 | 1695 | 1743 |
| Mean (SD) | 3.3 (5.33) | 2.5 (3.39) | 2.5 (3.45) |
| Median | 1.0 | 2.0 | 2.0 |
| Min, Max | 1, 32 | 1, 58 | 1, 58 |
| Lymphadenopathy [1] | | | |
| n | 534 | 1956 | 2490 |
| Mean (SD) | 2.6 (4.65) | 2.4 (2.86) | 2.4 (3.32) |
| Median | 1.0 | 2.0 | 1.5 |
| Min, Max | 1, 76 | 1, 54 | 1, 76 |
| Solicited Systemic Adverse Reactions | | | |
| n | 5069 | 11064 | 16133 |
| Mean (SD) | 3.3 (4.77) | 3.1 (4.04) | 3.1 (4.28) |
| Median | 2.0 | 2.0 | 2.0 |
| Min, Max | 1, 70 | 1, 72 | 1, 72 |
| Fever | | | |
| n | 43 | 2172 | 2215 |
| Mean (SD) | 1.3 (0.54) | 1.2 (1.82) | 1.2 (1.80) |
| Median | 1.0 | 1.0 | 1.0 |
| Min, Max | 1, 3 | 1, 58 | 1, 58 |

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

| Solicited Adverse Reaction Category Statistic | Placebo (N=13870) | mRNA-1273 (N=13947) | Total (N=27817) |
|---|----------------------|------------------------|--------------------|
| Headache | | | |
| n | 3252 | 8165 | 11417 |
| Mean (SD) | 2.3 (2.77) | 2.3 (2.80) | 2.3 (2.79) |
| Median | 1.0 | 2.0 | 2.0 |
| Min, Max | 1, 58 | 1, 65 | 1, 65 |
| Fatigue | | | |
| n | 3225 | 9096 | 12321 |
| Mean (SD) | 2.9 (4.29) | 2.6 (3.41) | 2.7 (3.67) |
| Median | 2.0 | 2.0 | 2.0 |
| Min, Max | 1, 69 | 1, 65 | 1, 69 |
| Myalgia | | | |
| n | 1697 | 8036 | 9733 |
| Mean (SD) | 3.1 (5.34) | 2.1 (2.95) | 2.3 (3.51) |
| Median | 2.0 | 1.0 | 2.0 |
| Min, Max | 1, 64 | 1, 65 | 1, 65 |
| Arthralgia | | | |
| n | 1468 | 5937 | 7405 |
| Mean (SD) | 3.6 (6.06) | 2.2 (3.04) | 2.5 (3.87) |
| Median | 2.0 | 1.0 | 1.0 |
| Min, Max | 1, 64 | 1, 70 | 1, 70 |

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

| Solicited Adverse Reaction Category Statistic | Placebo (N=13870) | mRNA-1273 (N=13947) | Total (N=27817) |
|---|----------------------|------------------------|--------------------|
| Nausea/Vomiting | | | |
| n | 883 | 2634 | 3517 |
| Mean (SD) | 1.9 (3.25) | 1.7 (2.08) | 1.7 (2.43) |
| Median | 1.0 | 1.0 | 1.0 |
| Min, Max | 1, 58 | 1, 64 | 1, 64 |
| Chills | | | |
| n | 755 | 6100 | 6855 |
| Mean (SD) | 1.9 (2.75) | 1.5 (1.86) | 1.5 (1.98) |
| Median | 1.0 | 1.0 | 1.0 |
| Min, Max | 1, 58 | 1, 64 | 1, 64 |

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection
Solicited Safety Set

| Solicited Adverse Reaction Category Statistic | Placebo (N=15162) | mRNA-1273 (N=15176) | Total (N=30339) |
|---|----------------------|------------------------|--------------------|
| Solicited Adverse Reactions | | | |
| n | 9027 | 14338 | 23365 |
| Mean (SD) | 3.5 (4.89) | 4.4 (4.54) | 4.1 (4.70) |
| Median | 2.0 | 4.0 | 3.0 |
| Min, Max | 1, 76 | 1, 72 | 1, 76 |
| Solicited Local Adverse Reactions | | | |
| n | 4381 | 13962 | 18343 |
| Mean (SD) | 2.1 (3.12) | 3.4 (2.73) | 3.1 (2.88) |
| Median | 1.0 | 3.0 | 3.0 |
| Min, Max | 1, 76 | 1, 64 | 1, 76 |
| Pain | | | |
| n | 3975 | 13901 | 17876 |
| Mean (SD) | 1.8 (2.55) | 3.1 (2.07) | 2.8 (2.26) |
| Median | 1.0 | 3.0 | 3.0 |
| Min, Max | 1, 58 | 1, 64 | 1, 64 |
| Erythema (Redness) | | | |
| n | 114 | 1470 | 1584 |
| Mean (SD) | 2.2 (4.47) | 2.6 (3.39) | 2.6 (3.48) |
| Median | 1.0 | 2.0 | 2.0 |
| Min, Max | 1, 38 | 1, 57 | 1, 57 |

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection
Solicited Safety Set

| Solicited Adverse Reaction Category Statistic | Placebo (N=15162) | mRNA-1273 (N=15176) | Total (N=30339) |
|---|----------------------|------------------------|--------------------|
| Swelling (Hardness) | | | |
| n | 95 | 2183 | 2278 |
| Mean (SD) | 3.7 (6.29) | 2.5 (3.23) | 2.5 (3.42) |
| Median | 1.0 | 2.0 | 2.0 |
| Min, Max | 1, 32 | 1, 58 | 1, 58 |
| Lymphadenopathy [1] | | | |
| n | 1074 | 2914 | 3988 |
| Mean (SD) | 2.3 (3.74) | 2.4 (2.95) | 2.3 (3.18) |
| Median | 1.0 | 1.0 | 1.0 |
| Min, Max | 1, 76 | 1, 54 | 1, 76 |
| Solicited Systemic Adverse Reactions | | | |
| n | 8032 | 12553 | 20585 |
| Mean (SD) | 3.5 (4.81) | 3.4 (4.45) | 3.5 (4.59) |
| Median | 2.0 | 2.0 | 2.0 |
| Min, Max | 1, 74 | 1, 72 | 1, 74 |
| Fever | | | |
| n | 88 | 2252 | 2340 |
| Mean (SD) | 1.3 (0.58) | 1.2 (1.79) | 1.2 (1.76) |
| Median | 1.0 | 1.0 | 1.0 |
| Min, Max | 1, 3 | 1, 58 | 1, 58 |

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection
Solicited Safety Set

| Solicited Adverse Reaction Category Statistic | Placebo (N=15162) | mRNA-1273 (N=15176) | Total (N=30339) |
|---|----------------------|------------------------|--------------------|
| Headache | | | |
| n | 5527 | 9566 | 15093 |
| Mean (SD) | 2.3 (2.78) | 2.4 (2.89) | 2.4 (2.85) |
| Median | 2.0 | 2.0 | 2.0 |
| Min, Max | 1, 58 | 1, 65 | 1, 65 |
| Fatigue | | | |
| n | 5470 | 10393 | 15863 |
| Mean (SD) | 3.0 (4.33) | 2.9 (3.85) | 2.9 (4.02) |
| Median | 2.0 | 2.0 | 2.0 |
| Min, Max | 1, 74 | 1, 69 | 1, 74 |
| Myalgia | | | |
| n | 3052 | 9039 | 12091 |
| Mean (SD) | 2.9 (4.69) | 2.3 (3.23) | 2.4 (3.67) |
| Median | 2.0 | 2.0 | 2.0 |
| Min, Max | 1, 64 | 1, 65 | 1, 65 |
| Arthralgia | | | |
| n | 2606 | 6803 | 9409 |
| Mean (SD) | 3.4 (5.50) | 2.4 (3.46) | 2.7 (4.15) |
| Median | 2.0 | 1.0 | 2.0 |
| Min, Max | 1, 64 | 1, 70 | 1, 70 |

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection
Solicited Safety Set

| Solicited Adverse Reaction Category Statistic | Placebo (N=15162) | mRNA-1273 (N=15176) | Total (N=30339) |
|---|----------------------|------------------------|--------------------|
| Nausea/Vomiting | | | |
| n | 1679 | 3366 | 5045 |
| Mean (SD) | 1.9 (2.78) | 1.7 (2.03) | 1.8 (2.31) |
| Median | 1.0 | 1.0 | 1.0 |
| Min, Max | 1, 58 | 1, 64 | 1, 64 |
| Chills | | | |
| n | 1439 | 6580 | 8019 |
| Mean (SD) | 1.8 (2.20) | 1.5 (1.91) | 1.6 (1.97) |
| Median | 1.0 | 1.0 | 1.0 |
| Min, Max | 1, 58 | 1, 64 | 1, 64 |

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Grade
First Injection Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=15154) n (%) | mRNA-1273 (N=15167) n (%) | Total (N=30322) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Solicited Adverse Reactions - N1 | 15154 | 15167 | 30322 |
| Any Solicited Adverse Reactions | 926 (6.1) | 1113 (7.3) | 2039 (6.7) |
| 95% CI | 5.7, 6.5 | 6.9, 7.8 | 6.4, 7.0 |
| Grade 1 | 413 (2.7) | 506 (3.3) | 919 (3.0) |
| Grade 2 | 415 (2.7) | 496 (3.3) | 911 (3.0) |
| Grade 3 | 98 (0.6) | 111 (0.7) | 209 (0.7) |
| Grade 4 | 0 | 0 | 0 |
| Solicited Local Adverse Reactions - N1 | 15150 | 15163 | 30314 |
| Any Solicited Local Adverse Reactions | 109 (0.7) | 328 (2.2) | 437 (1.4) |
| 95% CI | 0.6, 0.9 | 1.9, 2.4 | 1.3, 1.6 |
| Grade 1 | 82 (0.5) | 228 (1.5) | 310 (1.0) |
| Grade 2 | 23 (0.2) | 80 (0.5) | 103 (0.3) |
| Grade 3 | 4 (<0.1) | 20 (0.1) | 24 (<0.1) |
| Grade 4 | 0 | 0 | 0 |
| Pain - N1 | 15150 | 15163 | 30314 |
| Any | 49 (0.3) | 89 (0.6) | 138 (0.5) |
| Grade 1 | 39 (0.3) | 48 (0.3) | 87 (0.3) |
| Grade 2 | 8 (<0.1) | 32 (0.2) | 40 (0.1) |
| Grade 3 | 2 (<0.1) | 9 (<0.1) | 11 (<0.1) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Grade
First Injection Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=15154) n (%) | mRNA-1273 (N=15167) n (%) | Total (N=30322) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Erythema (Redness) - N1 | 15150 | 15162 | 30313 |
| Any | 5 (<0.1) | 19 (0.1) | 24 (<0.1) |
| Grade 1 | 3 (<0.1) | 9 (<0.1) | 12 (<0.1) |
| Grade 2 | 1 (<0.1) | 7 (<0.1) | 8 (<0.1) |
| Grade 3 | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Grade 4 | 0 | 0 | 0 |
| Swelling (Hardness) - N1 | 15150 | 15162 | 30313 |
| Any | 10 (<0.1) | 21 (0.1) | 31 (0.1) |
| Grade 1 | 6 (<0.1) | 13 (<0.1) | 19 (<0.1) |
| Grade 2 | 2 (<0.1) | 8 (<0.1) | 10 (<0.1) |
| Grade 3 | 2 (<0.1) | 0 | 2 (<0.1) |
| Grade 4 | 0 | 0 | 0 |
| Lymphadenopathy - N1 [1] | 15150 | 15162 | 30313 |
| Any | 57 (0.4) | 234 (1.5) | 291 (1.0) |
| Grade 1 | 44 (0.3) | 181 (1.2) | 225 (0.7) |
| Grade 2 | 13 (<0.1) | 44 (0.3) | 57 (0.2) |
| Grade 3 | 0 | 9 (<0.1) | 9 (<0.1) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Grade
First Injection Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=15154) n (%) | mRNA-1273 (N=15167) n (%) | Total (N=30322) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Solicited Systemic Adverse Reactions - N1 | 15154 | 15166 | 30321 |
| Any Solicited Systemic Adverse Reactions | 856 (5.6) | 879 (5.8) | 1735 (5.7) |
| 95% CI | 5.3, 6.0 | 5.4, 6.2 | 5.5, 6.0 |
| Grade 1 | 359 (2.4) | 334 (2.2) | 693 (2.3) |
| Grade 2 | 402 (2.7) | 447 (2.9) | 849 (2.8) |
| Grade 3 | 95 (0.6) | 98 (0.6) | 193 (0.6) |
| Grade 4 | 0 | 0 | 0 |
| Fever - N1 | 15152 | 15163 | 30316 |
| Any | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Grade 1 | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Grade 2 | 0 | 1 (<0.1) | 1 (<0.1) |
| Grade 3 | 0 | 1 (<0.1) | 1 (<0.1) |
| Grade 4 | 0 | 0 | 0 |
| Headache - N1 | 15149 | 15162 | 30312 |
| Any | 311 (2.1) | 340 (2.2) | 651 (2.1) |
| Grade 1 | 157 (1.0) | 178 (1.2) | 335 (1.1) |
| Grade 2 | 110 (0.7) | 125 (0.8) | 235 (0.8) |
| Grade 3 | 44 (0.3) | 37 (0.2) | 81 (0.3) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Grade
First Injection Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=15154) n (%) | mRNA-1273 (N=15167) n (%) | Total (N=30322) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Fatigue - N1 | 15149 | 15162 | 30312 |
| Any | 474 (3.1) | 523 (3.4) | 997 (3.3) |
| Grade 1 | 160 (1.1) | 154 (1.0) | 314 (1.0) |
| Grade 2 | 266 (1.8) | 315 (2.1) | 581 (1.9) |
| Grade 3 | 48 (0.3) | 54 (0.4) | 102 (0.3) |
| Grade 4 | 0 | 0 | 0 |
| Myalgia - N1 | 15149 | 15162 | 30312 |
| Any | 245 (1.6) | 227 (1.5) | 472 (1.6) |
| Grade 1 | 101 (0.7) | 83 (0.5) | 184 (0.6) |
| Grade 2 | 122 (0.8) | 112 (0.7) | 234 (0.8) |
| Grade 3 | 22 (0.1) | 32 (0.2) | 54 (0.2) |
| Grade 4 | 0 | 0 | 0 |
| Arthralgia - N1 | 15149 | 15162 | 30312 |
| Any | 281 (1.9) | 249 (1.6) | 530 (1.7) |
| Grade 1 | 138 (0.9) | 104 (0.7) | 242 (0.8) |
| Grade 2 | 124 (0.8) | 119 (0.8) | 243 (0.8) |
| Grade 3 | 19 (0.1) | 26 (0.2) | 45 (0.1) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Grade
First Injection Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=15154) n (%) | mRNA-1273 (N=15167) n (%) | Total (N=30322) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Nausea/Vomiting - N1 | 15149 | 15162 | 30312 |
| Any | 66 (0.4) | 66 (0.4) | 132 (0.4) |
| Grade 1 | 40 (0.3) | 36 (0.2) | 76 (0.3) |
| Grade 2 | 25 (0.2) | 28 (0.2) | 53 (0.2) |
| Grade 3 | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Grade 4 | 0 | 0 | 0 |
| Chills - N1 | 15149 | 15162 | 30312 |
| Any | 46 (0.3) | 35 (0.2) | 81 (0.3) |
| Grade 1 | 26 (0.2) | 12 (<0.1) | 38 (0.1) |
| Grade 2 | 19 (0.1) | 18 (0.1) | 37 (0.1) |
| Grade 3 | 1 (<0.1) | 5 (<0.1) | 6 (<0.1) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=13870) n (%) | mRNA-1273 (N=13947) n (%) | Total (N=27817) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Solicited Adverse Reactions - N1 | 13870 | 13947 | 27817 |
| Any Solicited Adverse Reactions | 733 (5.3) | 967 (6.9) | 1700 (6.1) |
| 95% CI | 4.9, 5.7 | 6.5, 7.4 | 5.8, 6.4 |
| Grade 1 | 317 (2.3) | 223 (1.6) | 540 (1.9) |
| Grade 2 | 328 (2.4) | 483 (3.5) | 811 (2.9) |
| Grade 3 | 88 (0.6) | 260 (1.9) | 348 (1.3) |
| Grade 4 | 0 | 1 (<0.1) | 1 (<0.1) |
| Solicited Local Adverse Reactions - N1 | 13866 | 13944 | 27810 |
| Any Solicited Local Adverse Reactions | 105 (0.8) | 279 (2.0) | 384 (1.4) |
| 95% CI | 0.6, 0.9 | 1.8, 2.2 | 1.2, 1.5 |
| Grade 1 | 83 (0.6) | 105 (0.8) | 188 (0.7) |
| Grade 2 | 13 (<0.1) | 114 (0.8) | 127 (0.5) |
| Grade 3 | 9 (<0.1) | 60 (0.4) | 69 (0.2) |
| Grade 4 | 0 | 0 | 0 |
| Pain - N1 | 13866 | 13944 | 27810 |
| Any | 54 (0.4) | 149 (1.1) | 203 (0.7) |
| Grade 1 | 38 (0.3) | 52 (0.4) | 90 (0.3) |
| Grade 2 | 10 (<0.1) | 73 (0.5) | 83 (0.3) |
| Grade 3 | 6 (<0.1) | 24 (0.2) | 30 (0.1) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=13870) n (%) | mRNA-1273 (N=13947) n (%) | Total (N=27817) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Erythema (Redness) - N1 | 13866 | 13944 | 27810 |
| Any | 3 (<0.1) | 51 (0.4) | 54 (0.2) |
| Grade 1 | 3 (<0.1) | 8 (<0.1) | 11 (<0.1) |
| Grade 2 | 0 | 16 (0.1) | 16 (<0.1) |
| Grade 3 | 0 | 27 (0.2) | 27 (<0.1) |
| Grade 4 | 0 | 0 | 0 |
| Swelling (Hardness) - N1 | 13866 | 13944 | 27810 |
| Any | 8 (<0.1) | 44 (0.3) | 52 (0.2) |
| Grade 1 | 7 (<0.1) | 16 (0.1) | 23 (<0.1) |
| Grade 2 | 0 | 15 (0.1) | 15 (<0.1) |
| Grade 3 | 1 (<0.1) | 13 (<0.1) | 14 (<0.1) |
| Grade 4 | 0 | 0 | 0 |
| Lymphadenopathy - N1 [1] | 13866 | 13944 | 27810 |
| Any | 47 (0.3) | 85 (0.6) | 132 (0.5) |
| Grade 1 | 41 (0.3) | 58 (0.4) | 99 (0.4) |
| Grade 2 | 4 (<0.1) | 22 (0.2) | 26 (<0.1) |
| Grade 3 | 2 (<0.1) | 5 (<0.1) | 7 (<0.1) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=13870) n (%) | mRNA-1273 (N=13947) n (%) | Total (N=27817) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Solicited Systemic Adverse Reactions - N1 | 13869 | 13947 | 27816 |
| Any Solicited Systemic Adverse Reactions | 675 (4.9) | 796 (5.7) | 1471 (5.3) |
| 95% CI | 4.5, 5.2 | 5.3, 6.1 | 5.0, 5.6 |
| Grade 1 | 272 (2.0) | 155 (1.1) | 427 (1.5) |
| Grade 2 | 323 (2.3) | 429 (3.1) | 752 (2.7) |
| Grade 3 | 80 (0.6) | 211 (1.5) | 291 (1.0) |
| Grade 4 | 0 | 1 (<0.1) | 1 (<0.1) |
| Fever - N1 | 13864 | 13939 | 27803 |
| Any | 1 (<0.1) | 4 (<0.1) | 5 (<0.1) |
| Grade 1 | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Grade 2 | 0 | 1 (<0.1) | 1 (<0.1) |
| Grade 3 | 0 | 1 (<0.1) | 1 (<0.1) |
| Grade 4 | 0 | 0 | 0 |
| Headache - N1 | 13866 | 13944 | 27810 |
| Any | 289 (2.1) | 371 (2.7) | 660 (2.4) |
| Grade 1 | 145 (1.0) | 98 (0.7) | 243 (0.9) |
| Grade 2 | 116 (0.8) | 217 (1.6) | 333 (1.2) |
| Grade 3 | 28 (0.2) | 56 (0.4) | 84 (0.3) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=13870) n (%) | mRNA-1273 (N=13947) n (%) | Total (N=27817) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Fatigue - N1 | 13864 | 13944 | 27808 |
| Any | 370 (2.7) | 463 (3.3) | 833 (3.0) |
| Grade 1 | 116 (0.8) | 68 (0.5) | 184 (0.7) |
| Grade 2 | 207 (1.5) | 251 (1.8) | 458 (1.6) |
| Grade 3 | 47 (0.3) | 144 (1.0) | 191 (0.7) |
| Grade 4 | 0 | 0 | 0 |
| Myalgia - N1 | 13865 | 13944 | 27809 |
| Any | 212 (1.5) | 224 (1.6) | 436 (1.6) |
| Grade 1 | 83 (0.6) | 42 (0.3) | 125 (0.4) |
| Grade 2 | 104 (0.8) | 125 (0.9) | 229 (0.8) |
| Grade 3 | 25 (0.2) | 57 (0.4) | 82 (0.3) |
| Grade 4 | 0 | 0 | 0 |
| Arthralgia - N1 | 13864 | 13944 | 27808 |
| Any | 249 (1.8) | 249 (1.8) | 498 (1.8) |
| Grade 1 | 104 (0.8) | 56 (0.4) | 160 (0.6) |
| Grade 2 | 125 (0.9) | 146 (1.0) | 271 (1.0) |
| Grade 3 | 20 (0.1) | 47 (0.3) | 67 (0.2) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=13870) n (%) | mRNA-1273 (N=13947) n (%) | Total (N=27817) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Nausea/Vomiting - N1 | 13864 | 13944 | 27808 |
| Any | 49 (0.4) | 58 (0.4) | 107 (0.4) |
| Grade 1 | 20 (0.1) | 12 (<0.1) | 32 (0.1) |
| Grade 2 | 28 (0.2) | 40 (0.3) | 68 (0.2) |
| Grade 3 | 1 (<0.1) | 5 (<0.1) | 6 (<0.1) |
| Grade 4 | 0 | 1 (<0.1) | 1 (<0.1) |
| Chills - N1 | 13864 | 13944 | 27808 |
| Any | 48 (0.3) | 52 (0.4) | 100 (0.4) |
| Grade 1 | 22 (0.2) | 11 (<0.1) | 33 (0.1) |
| Grade 2 | 21 (0.2) | 32 (0.2) | 53 (0.2) |
| Grade 3 | 5 (<0.1) | 9 (<0.1) | 14 (<0.1) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Grade
Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=15162) n (%) | mRNA-1273 (N=15176) n (%) | Total (N=30339) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Solicited Adverse Reactions - N1 | 15162 | 15176 | 30339 |
| Any Solicited Adverse Reactions | 1436 (9.5) | 1811 (11.9) | 3247 (10.7) |
| 95% CI | 9.0, 9.9 | 11.4, 12.5 | 10.4, 11.1 |
| Grade 1 | 611 (4.0) | 603 (4.0) | 1214 (4.0) |
| Grade 2 | 647 (4.3) | 853 (5.6) | 1500 (4.9) |
| Grade 3 | 178 (1.2) | 354 (2.3) | 532 (1.8) |
| Grade 4 | 0 | 1 (<0.1) | 1 (<0.1) |
| Solicited Local Adverse Reactions - N1 | 15161 | 15176 | 30338 |
| Any Solicited Local Adverse Reactions | 196 (1.3) | 561 (3.7) | 757 (2.5) |
| 95% CI | 1.1, 1.5 | 3.4, 4.0 | 2.3, 2.7 |
| Grade 1 | 147 (1.0) | 303 (2.0) | 450 (1.5) |
| Grade 2 | 36 (0.2) | 178 (1.2) | 214 (0.7) |
| Grade 3 | 13 (<0.1) | 80 (0.5) | 93 (0.3) |
| Grade 4 | 0 | 0 | 0 |
| Pain - N1 | 15161 | 15176 | 30338 |
| Any | 97 (0.6) | 220 (1.4) | 317 (1.0) |
| Grade 1 | 71 (0.5) | 90 (0.6) | 161 (0.5) |
| Grade 2 | 18 (0.1) | 97 (0.6) | 115 (0.4) |
| Grade 3 | 8 (<0.1) | 33 (0.2) | 41 (0.1) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Grade
Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=15162) n (%) | mRNA-1273 (N=15176) n (%) | Total (N=30339) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Erythema (Redness) - N1 | 15161 | 15176 | 30338 |
| Any | 7 (<0.1) | 68 (0.4) | 75 (0.2) |
| Grade 1 | 5 (<0.1) | 16 (0.1) | 21 (<0.1) |
| Grade 2 | 1 (<0.1) | 22 (0.1) | 23 (<0.1) |
| Grade 3 | 1 (<0.1) | 30 (0.2) | 31 (0.1) |
| Grade 4 | 0 | 0 | 0 |
| Swelling (Hardness) - N1 | 15161 | 15176 | 30338 |
| Any | 17 (0.1) | 65 (0.4) | 82 (0.3) |
| Grade 1 | 12 (<0.1) | 29 (0.2) | 41 (0.1) |
| Grade 2 | 2 (<0.1) | 23 (0.2) | 25 (<0.1) |
| Grade 3 | 3 (<0.1) | 13 (<0.1) | 16 (<0.1) |
| Grade 4 | 0 | 0 | 0 |
| Lymphadenopathy - N1 [1] | 15161 | 15176 | 30338 |
| Any | 94 (0.6) | 296 (2.0) | 390 (1.3) |
| Grade 1 | 75 (0.5) | 221 (1.5) | 296 (1.0) |
| Grade 2 | 17 (0.1) | 61 (0.4) | 78 (0.3) |
| Grade 3 | 2 (<0.1) | 14 (<0.1) | 16 (<0.1) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Grade
Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=15162) n (%) | mRNA-1273 (N=15176) n (%) | Total (N=30339) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Solicited Systemic Adverse Reactions - N1 | 15162 | 15176 | 30339 |
| Any Solicited Systemic Adverse Reactions | 1325 (8.7) | 1468 (9.7) | 2793 (9.2) |
| 95% CI | 8.3, 9.2 | 9.2, 10.2 | 8.9, 9.5 |
| Grade 1 | 528 (3.5) | 410 (2.7) | 938 (3.1) |
| Grade 2 | 630 (4.2) | 763 (5.0) | 1393 (4.6) |
| Grade 3 | 167 (1.1) | 294 (1.9) | 461 (1.5) |
| Grade 4 | 0 | 1 (<0.1) | 1 (<0.1) |
| Fever - N1 | 15161 | 15175 | 30337 |
| Any | 4 (<0.1) | 7 (<0.1) | 11 (<0.1) |
| Grade 1 | 4 (<0.1) | 3 (<0.1) | 7 (<0.1) |
| Grade 2 | 0 | 2 (<0.1) | 2 (<0.1) |
| Grade 3 | 0 | 2 (<0.1) | 2 (<0.1) |
| Grade 4 | 0 | 0 | 0 |
| Headache - N1 | 15161 | 15176 | 30338 |
| Any | 555 (3.7) | 655 (4.3) | 1210 (4.0) |
| Grade 1 | 274 (1.8) | 243 (1.6) | 517 (1.7) |
| Grade 2 | 211 (1.4) | 320 (2.1) | 531 (1.8) |
| Grade 3 | 70 (0.5) | 92 (0.6) | 162 (0.5) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Grade
Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=15162) n (%) | mRNA-1273 (N=15176) n (%) | Total (N=30339) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Fatigue - N1 | 15161 | 15176 | 30338 |
| Any | 743 (4.9) | 874 (5.8) | 1617 (5.3) |
| Grade 1 | 237 (1.6) | 187 (1.2) | 424 (1.4) |
| Grade 2 | 415 (2.7) | 497 (3.3) | 912 (3.0) |
| Grade 3 | 91 (0.6) | 190 (1.3) | 281 (0.9) |
| Grade 4 | 0 | 0 | 0 |
| Myalgia - N1 | 15161 | 15176 | 30338 |
| Any | 410 (2.7) | 415 (2.7) | 825 (2.7) |
| Grade 1 | 158 (1.0) | 109 (0.7) | 267 (0.9) |
| Grade 2 | 205 (1.4) | 220 (1.4) | 425 (1.4) |
| Grade 3 | 47 (0.3) | 86 (0.6) | 133 (0.4) |
| Grade 4 | 0 | 0 | 0 |
| Arthralgia - N1 | 15161 | 15176 | 30338 |
| Any | 465 (3.1) | 439 (2.9) | 904 (3.0) |
| Grade 1 | 201 (1.3) | 129 (0.9) | 330 (1.1) |
| Grade 2 | 226 (1.5) | 243 (1.6) | 469 (1.5) |
| Grade 3 | 38 (0.3) | 67 (0.4) | 105 (0.3) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Grade
Solicited Safety Set

| Solicited Adverse Reaction Category Grade | Placebo (N=15162) n (%) | mRNA-1273 (N=15176) n (%) | Total (N=30339) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Nausea/Vomiting - N1 | 15161 | 15176 | 30338 |
| Any | 104 (0.7) | 118 (0.8) | 222 (0.7) |
| Grade 1 | 54 (0.4) | 44 (0.3) | 98 (0.3) |
| Grade 2 | 48 (0.3) | 66 (0.4) | 114 (0.4) |
| Grade 3 | 2 (<0.1) | 7 (<0.1) | 9 (<0.1) |
| Grade 4 | 0 | 1 (<0.1) | 1 (<0.1) |
| Chills - N1 | 15161 | 15176 | 30338 |
| Any | 89 (0.6) | 84 (0.6) | 173 (0.6) |
| Grade 1 | 46 (0.3) | 22 (0.1) | 68 (0.2) |
| Grade 2 | 37 (0.2) | 49 (0.3) | 86 (0.3) |
| Grade 3 | 6 (<0.1) | 13 (<0.1) | 19 (<0.1) |
| Grade 4 | 0 | 0 | 0 |

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 - 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 - 40 C; G4 = > 40 C.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.7.1
Summary of Unsolicited TEAE up to 28 Days After Any Injection
Safety Set

| | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Unsolicited TEAEs Regardless of Relationship to Study Vaccination | | | |
| All | 2949 (19.4) | 3325 (21.9) | 6274 (20.7) |
| Serious | 86 (0.6) | 82 (0.5) | 168 (0.6) |
| Fatal | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Medically-Attended | 1276 (8.4) | 1215 (8.0) | 2491 (8.2) |
| Leading to Discontinuation from Study Vaccine | 71 (0.5) | 41 (0.3) | 112 (0.4) |
| Leading to Discontinuation from Participation in the Study | 0 | 0 | 0 |
| Severe | 190 (1.3) | 216 (1.4) | 406 (1.3) |
| Unsolicited TEAEs Related to Study Vaccination | | | |
| All | 609 (4.0) | 1127 (7.4) | 1736 (5.7) |
| Serious | 4 (<0.1) | 5 (<0.1) | 9 (<0.1) |
| Fatal | 0 | 0 | 0 |
| Medically-Attended | 73 (0.5) | 122 (0.8) | 195 (0.6) |
| Leading to Discontinuation from Study Vaccine | 13 (<0.1) | 15 (<0.1) | 28 (<0.1) |
| Leading to Discontinuation from Participation in the Study | 0 | 0 | 0 |
| Severe | 29 (0.2) | 70 (0.5) | 99 (0.3) |

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.7.3
Summary of Unsolicited TEAE in Overall Stage
Safety Set

| | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Unsolicited TEAEs Regardless of Relationship to Study Vaccination | | | |
| All | 3291 (21.7) | 3567 (23.5) | 6858 (22.6) |
| Serious | 120 (0.8) | 113 (0.7) | 233 (0.8) |
| Fatal | 4 (<0.1) | 4 (<0.1) | 8 (<0.1) |
| Medically-Attended | 1529 (10.1) | 1414 (9.3) | 2943 (9.7) |
| Leading to Discontinuation from Study Vaccine | 85 (0.6) | 45 (0.3) | 130 (0.4) |
| Leading to Discontinuation from Participation in the Study | 0 | 0 | 0 |
| Severe | 236 (1.6) | 256 (1.7) | 492 (1.6) |
| Unsolicited TEAEs Related to Study Vaccination | | | |
| All | 624 (4.1) | 1137 (7.5) | 1761 (5.8) |
| Serious | 5 (<0.1) | 6 (<0.1) | 11 (<0.1) |
| Fatal | 0 | 0 | 0 |
| Medically-Attended | 77 (0.5) | 124 (0.8) | 201 (0.7) |
| Leading to Discontinuation from Study Vaccine | 14 (<0.1) | 15 (<0.1) | 29 (<0.1) |
| Leading to Discontinuation from Participation in the Study | 0 | 0 | 0 |
| Severe | 31 (0.2) | 71 (0.5) | 102 (0.3) |

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.7.4
Summary of Unsolicited TEAE by Age Group up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Unsolicited TEAEs Regardless of Relationship to Study Vaccination | | | |
| All | 2215 (19.4) | 2453 (21.5) | 4668 (20.4) |
| Serious | 44 (0.4) | 46 (0.4) | 90 (0.4) |
| Fatal | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Medically-Attended | 900 (7.9) | 879 (7.7) | 1779 (7.8) |
| Leading to Discontinuation from Study Vaccine | 54 (0.5) | 29 (0.3) | 83 (0.4) |
| Leading to Discontinuation from Participation in the Study | 0 | 0 | 0 |
| Severe | 120 (1.1) | 142 (1.2) | 262 (1.1) |
| Unsolicited TEAEs Related to Study Vaccination | | | |
| All | 471 (4.1) | 866 (7.6) | 1337 (5.9) |
| Serious | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Fatal | 0 | 0 | 0 |
| Medically-Attended | 60 (0.5) | 100 (0.9) | 160 (0.7) |
| Leading to Discontinuation from Study Vaccine | 9 (<0.1) | 12 (0.1) | 21 (<0.1) |
| Leading to Discontinuation from Participation in the Study | 0 | 0 | 0 |
| Severe | 19 (0.2) | 49 (0.4) | 68 (0.3) |

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.7.4
Summary of Unsolicited TEAE by Age Group up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--|------------------------------|--------------------------------|----------------------------|
| Unsolicited TEAEs Regardless of Relationship to Study Vaccination | | | |
| All | 734 (19.6) | 872 (23.1) | 1606 (21.4) |
| Serious | 42 (1.1) | 36 (1.0) | 78 (1.0) |
| Fatal | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Medically-Attended | 376 (10.0) | 336 (8.9) | 712 (9.5) |
| Leading to Discontinuation from Study Vaccine | 17 (0.5) | 12 (0.3) | 29 (0.4) |
| Leading to Discontinuation from Participation in the Study | 0 | 0 | 0 |
| Severe | 70 (1.9) | 74 (2.0) | 144 (1.9) |
| Unsolicited TEAEs Related to Study Vaccination | | | |
| All | 138 (3.7) | 261 (6.9) | 399 (5.3) |
| Serious | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Fatal | 0 | 0 | 0 |
| Medically-Attended | 13 (0.3) | 22 (0.6) | 35 (0.5) |
| Leading to Discontinuation from Study Vaccine | 4 (0.1) | 3 (<0.1) | 7 (<0.1) |
| Leading to Discontinuation from Participation in the Study | 0 | 0 | 0 |
| Severe | 10 (0.3) | 21 (0.6) | 31 (0.4) |

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Number of Subjects Reporting Unsolicited Adverse Events | 2949 (19.4) | 3325 (21.9) | 6274 (20.7) |
| Number of Unsolicited Adverse Events | 5348 | 6157 | 11505 |
| Infections and infestations | 621 (4.1) | 521 (3.4) | 1142 (3.8) |
| Urinary tract infection | 85 (0.6) | 70 (0.5) | 155 (0.5) |
| Sinusitis | 27 (0.2) | 52 (0.3) | 79 (0.3) |
| Upper respiratory tract infection | 62 (0.4) | 40 (0.3) | 102 (0.3) |
| Viral infection | 31 (0.2) | 22 (0.1) | 53 (0.2) |
| COVID-19 | 105 (0.7) | 19 (0.1) | 124 (0.4) |
| Herpes zoster | 10 (<0.1) | 18 (0.1) | 28 (<0.1) |
| Gastroenteritis | 14 (<0.1) | 16 (0.1) | 30 (<0.1) |
| Tooth infection | 11 (<0.1) | 16 (0.1) | 27 (<0.1) |
| Rhinovirus infection | 4 (<0.1) | 15 (<0.1) | 19 (<0.1) |
| Tooth abscess | 22 (0.1) | 15 (<0.1) | 37 (0.1) |
| Pharyngitis | 18 (0.1) | 14 (<0.1) | 32 (0.1) |
| Cellulitis | 11 (<0.1) | 12 (<0.1) | 23 (<0.1) |
| Conjunctivitis | 6 (<0.1) | 12 (<0.1) | 18 (<0.1) |
| Ear infection | 7 (<0.1) | 12 (<0.1) | 19 (<0.1) |
| Pharyngitis streptococcal | 16 (0.1) | 11 (<0.1) | 27 (<0.1) |
| Gingivitis | 4 (<0.1) | 9 (<0.1) | 13 (<0.1) |
| Hordeolum | 9 (<0.1) | 8 (<0.1) | 17 (<0.1) |
| Oral herpes | 5 (<0.1) | 8 (<0.1) | 13 (<0.1) |
| Fungal infection | 8 (<0.1) | 7 (<0.1) | 15 (<0.1) |

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Infections and infestations (Cont.) | | | |
| Diverticulitis | 8 (<0.1) | 6 (<0.1) | 14 (<0.1) |
| Herpes simplex | 1 (<0.1) | 6 (<0.1) | 7 (<0.1) |
| Pneumonia | 8 (<0.1) | 6 (<0.1) | 14 (<0.1) |
| Viral upper respiratory tract infection | 9 (<0.1) | 6 (<0.1) | 15 (<0.1) |
| Acute sinusitis | 3 (<0.1) | 5 (<0.1) | 8 (<0.1) |
| Bacterial vaginosis | 5 (<0.1) | 5 (<0.1) | 10 (<0.1) |
| Folliculitis | 4 (<0.1) | 5 (<0.1) | 9 (<0.1) |
| Localised infection | 8 (<0.1) | 5 (<0.1) | 13 (<0.1) |
| Otitis media | 6 (<0.1) | 5 (<0.1) | 11 (<0.1) |
| Paronychia | 2 (<0.1) | 5 (<0.1) | 7 (<0.1) |
| Vulvovaginal candidiasis | 2 (<0.1) | 5 (<0.1) | 7 (<0.1) |
| Enterovirus infection | 0 | 4 (<0.1) | 4 (<0.1) |
| Respiratory tract infection | 4 (<0.1) | 4 (<0.1) | 8 (<0.1) |
| Rhinitis | 9 (<0.1) | 4 (<0.1) | 13 (<0.1) |
| Staphylococcal infection | 1 (<0.1) | 4 (<0.1) | 5 (<0.1) |
| Subcutaneous abscess | 1 (<0.1) | 4 (<0.1) | 5 (<0.1) |
| Abscess limb | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Asymptomatic COVID-19 | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Helicobacter infection | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Impetigo | 0 | 3 (<0.1) | 3 (<0.1) |
| Injection site cellulitis | 0 | 3 (<0.1) | 3 (<0.1) |
| Laryngitis | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Nasopharyngitis | 9 (<0.1) | 3 (<0.1) | 12 (<0.1) |
| Onychomycosis | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Infections and infestations (Cont.) | | | |
| Skin infection | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Vulvovaginal mycotic infection | 9 (<0.1) | 3 (<0.1) | 12 (<0.1) |
| Bronchitis | 5 (<0.1) | 2 (<0.1) | 7 (<0.1) |
| Chlamydial infection | 0 | 2 (<0.1) | 2 (<0.1) |
| Chronic sinusitis | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Clostridium difficile infection | 0 | 2 (<0.1) | 2 (<0.1) |
| Cystitis | 6 (<0.1) | 2 (<0.1) | 8 (<0.1) |
| Kidney infection | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Lyme disease | 0 | 2 (<0.1) | 2 (<0.1) |
| Oral candidiasis | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Otitis externa | 10 (<0.1) | 2 (<0.1) | 12 (<0.1) |
| Otitis media acute | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Soft tissue infection | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Staphylococcal skin infection | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Tinea pedis | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Tonsillitis | 7 (<0.1) | 2 (<0.1) | 9 (<0.1) |
| Upper respiratory tract infection bacterial | 0 | 2 (<0.1) | 2 (<0.1) |
| Viral rhinitis | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Abscess jaw | 0 | 1 (<0.1) | 1 (<0.1) |
| Appendicitis | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Bacterial infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Body tinea | 0 | 1 (<0.1) | 1 (<0.1) |
| Candida infection | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Cat scratch disease | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Infections and infestations (Cont.) | | | |
| Catheter site infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Clostridium difficile colitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Conjunctivitis bacterial | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Dermatophytosis of nail | 0 | 1 (<0.1) | 1 (<0.1) |
| Epididymitis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Furuncle | 0 | 1 (<0.1) | 1 (<0.1) |
| Gastroenteritis viral | 6 (<0.1) | 1 (<0.1) | 7 (<0.1) |
| Genital herpes | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Gonorrhoea | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Hepatitis A | 0 | 1 (<0.1) | 1 (<0.1) |
| Infected bite | 0 | 1 (<0.1) | 1 (<0.1) |
| Infected cyst | 0 | 1 (<0.1) | 1 (<0.1) |
| Infected dermal cyst | 0 | 1 (<0.1) | 1 (<0.1) |
| Joint abscess | 0 | 1 (<0.1) | 1 (<0.1) |
| Large intestine infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Laryngitis viral | 0 | 1 (<0.1) | 1 (<0.1) |
| Latent tuberculosis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Osteomyelitis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Parainfluenzae virus infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Parotitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Periodontitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Pharyngitis bacterial | 0 | 1 (<0.1) | 1 (<0.1) |
| Pneumonia staphylococcal | 0 | 1 (<0.1) | 1 (<0.1) |
| Proctitis chlamydial | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Infections and infestations (Cont.) | | | |
| Respiratory tract infection viral | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Rocky mountain spotted fever | 0 | 1 (<0.1) | 1 (<0.1) |
| Sepsis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Sexually transmitted disease | 0 | 1 (<0.1) | 1 (<0.1) |
| Sialoadenitis | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Toxic shock syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaginal infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Viral pharyngitis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Wound infection | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Blastocystis infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Breast abscess | 1 (<0.1) | 0 | 1 (<0.1) |
| Breast cellulitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Campylobacter infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Corneal infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Denture stomatitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Eye infection | 4 (<0.1) | 0 | 4 (<0.1) |
| Fungal skin infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Gardnerella infection | 2 (<0.1) | 0 | 2 (<0.1) |
| Gastrointestinal viral infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Genital herpes simplex | 1 (<0.1) | 0 | 1 (<0.1) |
| Herpes virus infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Influenza | 1 (<0.1) | 0 | 1 (<0.1) |
| Labyrinthitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Mastoiditis | 1 (<0.1) | 0 | 1 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Infections and infestations (Cont.) | | | |
| Nasal abscess | 1 (<0.1) | 0 | 1 (<0.1) |
| Ophthalmic herpes zoster | 1 (<0.1) | 0 | 1 (<0.1) |
| Pelvic abscess | 1 (<0.1) | 0 | 1 (<0.1) |
| Post procedural infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Pustule | 1 (<0.1) | 0 | 1 (<0.1) |
| Pyelonephritis acute | 1 (<0.1) | 0 | 1 (<0.1) |
| Root canal infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Septic shock | 1 (<0.1) | 0 | 1 (<0.1) |
| Sinusitis bacterial | 1 (<0.1) | 0 | 1 (<0.1) |
| Skin candida | 1 (<0.1) | 0 | 1 (<0.1) |
| Streptococcal infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Streptococcal sepsis | 1 (<0.1) | 0 | 1 (<0.1) |
| Suspected COVID-19 | 2 (<0.1) | 0 | 2 (<0.1) |
| Syphilis | 1 (<0.1) | 0 | 1 (<0.1) |
| Tinea cruris | 1 (<0.1) | 0 | 1 (<0.1) |
| Tinea infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Tinea versicolour | 1 (<0.1) | 0 | 1 (<0.1) |
| Varicella zoster virus infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 32 (0.2) | 37 (0.2) | 69 (0.2) |
| Basal cell carcinoma | 11 (<0.1) | 6 (<0.1) | 17 (<0.1) |
| Squamous cell carcinoma | 6 (<0.1) | 3 (<0.1) | 9 (<0.1) |
| Malignant melanoma | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.) | | | |
| Melanocytic naevus | 0 | 2 (<0.1) | 2 (<0.1) |
| Prostate cancer | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Uterine leiomyoma | 0 | 2 (<0.1) | 2 (<0.1) |
| Benign hepatic neoplasm | 0 | 1 (<0.1) | 1 (<0.1) |
| Benign neoplasm of thyroid gland | 0 | 1 (<0.1) | 1 (<0.1) |
| Breast neoplasm | 0 | 1 (<0.1) | 1 (<0.1) |
| Chronic lymphocytic leukaemia | 0 | 1 (<0.1) | 1 (<0.1) |
| Chronic myelomonocytic leukaemia | 0 | 1 (<0.1) | 1 (<0.1) |
| Cutaneous lymphoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Haemangioma of liver | 0 | 1 (<0.1) | 1 (<0.1) |
| Keratoacanthoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Lip squamous cell carcinoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Lipoma | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Lipoma of breast | 0 | 1 (<0.1) | 1 (<0.1) |
| Lung cancer metastatic | 0 | 1 (<0.1) | 1 (<0.1) |
| Malignant melanoma in situ | 0 | 1 (<0.1) | 1 (<0.1) |
| Meningioma benign | 0 | 1 (<0.1) | 1 (<0.1) |
| Nasopharyngeal neoplasm benign | 0 | 1 (<0.1) | 1 (<0.1) |
| Neoplasm malignant | 0 | 1 (<0.1) | 1 (<0.1) |
| Pelvic neoplasm | 0 | 1 (<0.1) | 1 (<0.1) |
| Rectal cancer | 0 | 1 (<0.1) | 1 (<0.1) |
| Skin papilloma | 0 | 1 (<0.1) | 1 (<0.1) |
| Thyroid cancer | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.) | | | |
| Benign neoplasm of skin | 1 (<0.1) | 0 | 1 (<0.1) |
| Bladder neoplasm | 1 (<0.1) | 0 | 1 (<0.1) |
| Breast cancer | 1 (<0.1) | 0 | 1 (<0.1) |
| Breast cancer stage I | 1 (<0.1) | 0 | 1 (<0.1) |
| Chondromatosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Intraductal proliferative breast lesion | 1 (<0.1) | 0 | 1 (<0.1) |
| Prolactin-producing pituitary tumour | 1 (<0.1) | 0 | 1 (<0.1) |
| Skin cancer | 1 (<0.1) | 0 | 1 (<0.1) |
| Squamous cell carcinoma of skin | 2 (<0.1) | 0 | 2 (<0.1) |
| Blood and lymphatic system disorders | 62 (0.4) | 111 (0.7) | 173 (0.6) |
| Lymphadenopathy | 53 (0.3) | 92 (0.6) | 145 (0.5) |
| Anaemia | 0 | 7 (<0.1) | 7 (<0.1) |
| Lymph node pain | 3 (<0.1) | 5 (<0.1) | 8 (<0.1) |
| Lymphadenitis | 1 (<0.1) | 5 (<0.1) | 6 (<0.1) |
| Blood loss anaemia | 0 | 1 (<0.1) | 1 (<0.1) |
| Iron deficiency anaemia | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Leukocytosis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Splenomegaly | 0 | 1 (<0.1) | 1 (<0.1) |
| Thrombocytopenia | 0 | 1 (<0.1) | 1 (<0.1) |
| Increased tendency to bruise | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Immune system disorders | 30 (0.2) | 26 (0.2) | 56 (0.2) |
| Seasonal allergy | 20 (0.1) | 15 (<0.1) | 35 (0.1) |
| Hypersensitivity | 1 (<0.1) | 6 (<0.1) | 7 (<0.1) |
| Allergy to arthropod bite | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Autoimmune disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Drug hypersensitivity | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Food allergy | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Type IV hypersensitivity reaction | 0 | 1 (<0.1) | 1 (<0.1) |
| Allergy to chemicals | 1 (<0.1) | 0 | 1 (<0.1) |
| Allergy to plants | 1 (<0.1) | 0 | 1 (<0.1) |
| Anaphylactic reaction | 1 (<0.1) | 0 | 1 (<0.1) |
| Smoke sensitivity | 1 (<0.1) | 0 | 1 (<0.1) |
| Endocrine disorders | 9 (<0.1) | 5 (<0.1) | 14 (<0.1) |
| Hypothyroidism | 5 (<0.1) | 4 (<0.1) | 9 (<0.1) |
| Thyroid cyst | 0 | 1 (<0.1) | 1 (<0.1) |
| Addison's disease | 1 (<0.1) | 0 | 1 (<0.1) |
| Androgen deficiency | 1 (<0.1) | 0 | 1 (<0.1) |
| Hypogonadism | 1 (<0.1) | 0 | 1 (<0.1) |
| Oestrogen deficiency | 1 (<0.1) | 0 | 1 (<0.1) |
| Metabolism and nutrition disorders | 65 (0.4) | 70 (0.5) | 135 (0.4) |
| Hyperlipidaemia | 9 (<0.1) | 12 (<0.1) | 21 (<0.1) |
| Type 2 diabetes mellitus | 3 (<0.1) | 10 (<0.1) | 13 (<0.1) |
| Decreased appetite | 6 (<0.1) | 9 (<0.1) | 15 (<0.1) |

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Metabolism and nutrition disorders (Cont.) | | | |
| Dehydration | 4 (<0.1) | 7 (<0.1) | 11 (<0.1) |
| Hypercholesterolaemia | 11 (<0.1) | 7 (<0.1) | 18 (<0.1) |
| Vitamin D deficiency | 7 (<0.1) | 7 (<0.1) | 14 (<0.1) |
| Diabetes mellitus | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Hyperglycaemia | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Hypertriglyceridaemia | 0 | 3 (<0.1) | 3 (<0.1) |
| Gout | 7 (<0.1) | 2 (<0.1) | 9 (<0.1) |
| Hyponatraemia | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Abnormal loss of weight | 0 | 1 (<0.1) | 1 (<0.1) |
| Diabetes mellitus inadequate control | 0 | 1 (<0.1) | 1 (<0.1) |
| Food intolerance | 0 | 1 (<0.1) | 1 (<0.1) |
| Glucose tolerance impaired | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Gluten sensitivity | 0 | 1 (<0.1) | 1 (<0.1) |
| Hypoglycaemia | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Hypokalaemia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Insulin resistance | 0 | 1 (<0.1) | 1 (<0.1) |
| Iron deficiency | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Magnesium deficiency | 0 | 1 (<0.1) | 1 (<0.1) |
| Vitamin B12 deficiency | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Abnormal weight gain | 1 (<0.1) | 0 | 1 (<0.1) |
| Calcium deficiency | 1 (<0.1) | 0 | 1 (<0.1) |
| Dyslipidaemia | 1 (<0.1) | 0 | 1 (<0.1) |
| Folate deficiency | 1 (<0.1) | 0 | 1 (<0.1) |
| Hypocalcaemia | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Metabolism and nutrition disorders (Cont.) | | | |
| Increased appetite | 1 (<0.1) | 0 | 1 (<0.1) |
| Polydipsia | 1 (<0.1) | 0 | 1 (<0.1) |
| Psychiatric disorders | 69 (0.5) | 91 (0.6) | 160 (0.5) |
| Anxiety | 23 (0.2) | 24 (0.2) | 47 (0.2) |
| Depression | 15 (<0.1) | 24 (0.2) | 39 (0.1) |
| Insomnia | 13 (<0.1) | 14 (<0.1) | 27 (<0.1) |
| Abnormal dreams | 1 (<0.1) | 5 (<0.1) | 6 (<0.1) |
| Sleep disorder | 0 | 5 (<0.1) | 5 (<0.1) |
| Attention deficit hyperactivity disorder | 4 (<0.1) | 4 (<0.1) | 8 (<0.1) |
| Nightmare | 0 | 3 (<0.1) | 3 (<0.1) |
| Bipolar disorder | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Adjustment disorder with depressed mood | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Affect lability | 0 | 1 (<0.1) | 1 (<0.1) |
| Alcohol withdrawal syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Anxiety disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Bruxism | 0 | 1 (<0.1) | 1 (<0.1) |
| Completed suicide | 0 | 1 (<0.1) | 1 (<0.1) |
| Drug use disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Hallucination | 0 | 1 (<0.1) | 1 (<0.1) |
| Libido decreased | 0 | 1 (<0.1) | 1 (<0.1) |
| Major depression | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Panic attack | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Post-traumatic stress disorder | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Psychiatric disorders (Cont.) | | | |
| Schizoaffective disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Stress | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Substance abuse | 0 | 1 (<0.1) | 1 (<0.1) |
| Alcohol abuse | 1 (<0.1) | 0 | 1 (<0.1) |
| Confusional state | 1 (<0.1) | 0 | 1 (<0.1) |
| Generalised anxiety disorder | 2 (<0.1) | 0 | 2 (<0.1) |
| Mental fatigue | 1 (<0.1) | 0 | 1 (<0.1) |
| Mental status changes | 2 (<0.1) | 0 | 2 (<0.1) |
| Persistent depressive disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Psychotic disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Seasonal affective disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Suicidal ideation | 1 (<0.1) | 0 | 1 (<0.1) |
| Nervous system disorders | 552 (3.6) | 624 (4.1) | 1176 (3.9) |
| Headache | 409 (2.7) | 435 (2.9) | 844 (2.8) |
| Dizziness | 44 (0.3) | 61 (0.4) | 105 (0.3) |
| Paraesthesia | 19 (0.1) | 24 (0.2) | 43 (0.1) |
| Dysgeusia | 6 (<0.1) | 11 (<0.1) | 17 (<0.1) |
| Sinus headache | 5 (<0.1) | 11 (<0.1) | 16 (<0.1) |
| Ageusia | 6 (<0.1) | 10 (<0.1) | 16 (<0.1) |
| Migraine | 19 (0.1) | 10 (<0.1) | 29 (<0.1) |
| Sciatica | 5 (<0.1) | 10 (<0.1) | 15 (<0.1) |
| Hypoaesthesia | 4 (<0.1) | 8 (<0.1) | 12 (<0.1) |
| Syncope | 11 (<0.1) | 8 (<0.1) | 19 (<0.1) |

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Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Nervous system disorders (Cont.) | | | |
| Anosmia | 5 (<0.1) | 7 (<0.1) | 12 (<0.1) |
| Tension headache | 2 (<0.1) | 7 (<0.1) | 9 (<0.1) |
| Hyperaesthesia | 0 | 6 (<0.1) | 6 (<0.1) |
| Presyncope | 10 (<0.1) | 6 (<0.1) | 16 (<0.1) |
| Carpal tunnel syndrome | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Cervical radiculopathy | 0 | 3 (<0.1) | 3 (<0.1) |
| Mental impairment | 0 | 3 (<0.1) | 3 (<0.1) |
| Burning sensation | 0 | 2 (<0.1) | 2 (<0.1) |
| Disturbance in attention | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Neuralgia | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Seizure | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Somnolence | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Transient ischaemic attack | 0 | 2 (<0.1) | 2 (<0.1) |
| Amnesia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Balance disorder | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Carotid artery stenosis | 0 | 1 (<0.1) | 1 (<0.1) |
| Cerebrovascular accident | 0 | 1 (<0.1) | 1 (<0.1) |
| Cubital tunnel syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Diabetic neuropathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Dizziness postural | 0 | 1 (<0.1) | 1 (<0.1) |
| Embolic stroke | 0 | 1 (<0.1) | 1 (<0.1) |
| Essential tremor | 0 | 1 (<0.1) | 1 (<0.1) |
| Hyposmia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Idiopathic intracranial hypertension | 0 | 1 (<0.1) | 1 (<0.1) |

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Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Nervous system disorders (Cont.) | | | |
| Lethargy | 0 | 1 (<0.1) | 1 (<0.1) |
| Memory impairment | 0 | 1 (<0.1) | 1 (<0.1) |
| Migraine with aura | 0 | 1 (<0.1) | 1 (<0.1) |
| Migraine without aura | 0 | 1 (<0.1) | 1 (<0.1) |
| Movement disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Nerve compression | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Neuropathy peripheral | 0 | 1 (<0.1) | 1 (<0.1) |
| Parosmia | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Peripheral sensory neuropathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Poor quality sleep | 0 | 1 (<0.1) | 1 (<0.1) |
| Post-traumatic headache | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Primary headache associated with sexual activity | 0 | 1 (<0.1) | 1 (<0.1) |
| Small fibre neuropathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Tardive dyskinesia | 0 | 1 (<0.1) | 1 (<0.1) |
| Taste disorder | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Thoracic outlet syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Toxic encephalopathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Visual field defect | 0 | 1 (<0.1) | 1 (<0.1) |
| Basal ganglia haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Dysaesthesia | 3 (<0.1) | 0 | 3 (<0.1) |
| Encephalitis autoimmune | 1 (<0.1) | 0 | 1 (<0.1) |
| Facial paralysis | 1 (<0.1) | 0 | 1 (<0.1) |
| Head discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Horner's syndrome | 1 (<0.1) | 0 | 1 (<0.1) |

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|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Nervous system disorders (Cont.) | | | |
| Hypogeusia | 2 (<0.1) | 0 | 2 (<0.1) |
| Ischaemic stroke | 1 (<0.1) | 0 | 1 (<0.1) |
| Lumbar radiculopathy | 3 (<0.1) | 0 | 3 (<0.1) |
| Muscle contractions involuntary | 1 (<0.1) | 0 | 1 (<0.1) |
| Restless legs syndrome | 1 (<0.1) | 0 | 1 (<0.1) |
| Speech disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Tarsal tunnel syndrome | 1 (<0.1) | 0 | 1 (<0.1) |
| Tremor | 1 (<0.1) | 0 | 1 (<0.1) |
| Eye disorders | 46 (0.3) | 47 (0.3) | 93 (0.3) |
| Eye pruritus | 4 (<0.1) | 7 (<0.1) | 11 (<0.1) |
| Eye irritation | 0 | 5 (<0.1) | 5 (<0.1) |
| Dry eye | 5 (<0.1) | 2 (<0.1) | 7 (<0.1) |
| Eye inflammation | 0 | 2 (<0.1) | 2 (<0.1) |
| Eye pain | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Eye swelling | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Lacrimation increased | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Ocular hyperaemia | 6 (<0.1) | 2 (<0.1) | 8 (<0.1) |
| Retinal detachment | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Swelling of eyelid | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Vision blurred | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Visual impairment | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Vitreous floaters | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Accommodation disorder | 0 | 1 (<0.1) | 1 (<0.1) |

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Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Eye disorders (Cont.) | | | |
| Blepharitis | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Blepharospasm | 0 | 1 (<0.1) | 1 (<0.1) |
| Blindness transient | 0 | 1 (<0.1) | 1 (<0.1) |
| Conjunctival haemorrhage | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Conjunctival hyperaemia | 0 | 1 (<0.1) | 1 (<0.1) |
| Dry age-related macular degeneration | 0 | 1 (<0.1) | 1 (<0.1) |
| Eye discharge | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Eyelid cyst | 0 | 1 (<0.1) | 1 (<0.1) |
| Glaucoma | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Iris disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Noninfective conjunctivitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Photophobia | 0 | 1 (<0.1) | 1 (<0.1) |
| Vitreous disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Xerophthalmia | 0 | 1 (<0.1) | 1 (<0.1) |
| Conjunctival irritation | 1 (<0.1) | 0 | 1 (<0.1) |
| Conjunctivitis allergic | 2 (<0.1) | 0 | 2 (<0.1) |
| Conjunctivochalasis | 1 (<0.1) | 0 | 1 (<0.1) |
| Dacryoadenitis acquired | 1 (<0.1) | 0 | 1 (<0.1) |
| Dacryostenosis acquired | 1 (<0.1) | 0 | 1 (<0.1) |
| Eyelid ptosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Macular degeneration | 1 (<0.1) | 0 | 1 (<0.1) |
| Macular hole | 1 (<0.1) | 0 | 1 (<0.1) |
| Periorbital oedema | 1 (<0.1) | 0 | 1 (<0.1) |
| Periorbital pain | 1 (<0.1) | 0 | 1 (<0.1) |

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Eye disorders (Cont.) | | | |
| Periorbital swelling | 2 (<0.1) | 0 | 2 (<0.1) |
| Strabismus | 1 (<0.1) | 0 | 1 (<0.1) |
| Ulcerative keratitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Visual acuity reduced | 1 (<0.1) | 0 | 1 (<0.1) |
| Ear and labyrinth disorders | 54 (0.4) | 53 (0.3) | 107 (0.4) |
| Vertigo | 14 (<0.1) | 15 (<0.1) | 29 (<0.1) |
| Ear pain | 9 (<0.1) | 11 (<0.1) | 20 (<0.1) |
| Tinnitus | 8 (<0.1) | 8 (<0.1) | 16 (<0.1) |
| Vertigo positional | 0 | 6 (<0.1) | 6 (<0.1) |
| Cerumen impaction | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Ear canal erythema | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Ear discomfort | 5 (<0.1) | 2 (<0.1) | 7 (<0.1) |
| Middle ear effusion | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Motion sickness | 0 | 2 (<0.1) | 2 (<0.1) |
| Deafness neurosensory | 0 | 1 (<0.1) | 1 (<0.1) |
| Deafness unilateral | 0 | 1 (<0.1) | 1 (<0.1) |
| Ear congestion | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Eustachian tube dysfunction | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Otorrhoea | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Deafness | 1 (<0.1) | 0 | 1 (<0.1) |
| Ear haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Ear pruritus | 1 (<0.1) | 0 | 1 (<0.1) |
| Excessive cerumen production | 1 (<0.1) | 0 | 1 (<0.1) |

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Ear and labyrinth disorders (Cont.) | | | |
| Tympanic membrane perforation | 5 (<0.1) | 0 | 5 (<0.1) |
| Cardiac disorders | 55 (0.4) | 55 (0.4) | 110 (0.4) |
| Tachycardia | 10 (<0.1) | 12 (<0.1) | 22 (<0.1) |
| Bradycardia | 17 (0.1) | 10 (<0.1) | 27 (<0.1) |
| Atrial fibrillation | 7 (<0.1) | 9 (<0.1) | 16 (<0.1) |
| Palpitations | 5 (<0.1) | 6 (<0.1) | 11 (<0.1) |
| Angina pectoris | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Cardiac failure congestive | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Coronary artery disease | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Myocardial infarction | 0 | 3 (<0.1) | 3 (<0.1) |
| Arrhythmia | 4 (<0.1) | 2 (<0.1) | 6 (<0.1) |
| Sinus tachycardia | 0 | 2 (<0.1) | 2 (<0.1) |
| Acute coronary syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Acute myocardial infarction | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Cardiac failure | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Cardio-respiratory arrest | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Cardiomyopathy | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Chronic left ventricular failure | 0 | 1 (<0.1) | 1 (<0.1) |
| Ventricular extrasystoles | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Acute left ventricular failure | 1 (<0.1) | 0 | 1 (<0.1) |
| Atrial flutter | 1 (<0.1) | 0 | 1 (<0.1) |
| Atrial tachycardia | 1 (<0.1) | 0 | 1 (<0.1) |
| Cardiac failure acute | 1 (<0.1) | 0 | 1 (<0.1) |

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MedDRA version 23.0.

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Cardiac disorders (Cont.) | | | |
| Cardiac flutter | 1 (<0.1) | 0 | 1 (<0.1) |
| Ventricular fibrillation | 1 (<0.1) | 0 | 1 (<0.1) |
| Vascular disorders | 138 (0.9) | 149 (1.0) | 287 (0.9) |
| Hypertension | 105 (0.7) | 112 (0.7) | 217 (0.7) |
| Hot flush | 6 (<0.1) | 11 (<0.1) | 17 (<0.1) |
| Flushing | 3 (<0.1) | 7 (<0.1) | 10 (<0.1) |
| Haematoma | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Hypertensive urgency | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Hypotension | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Systolic hypertension | 4 (<0.1) | 3 (<0.1) | 7 (<0.1) |
| Achenbach syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Aortic aneurysm | 4 (<0.1) | 1 (<0.1) | 5 (<0.1) |
| Deep vein thrombosis | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Essential hypertension | 0 | 1 (<0.1) | 1 (<0.1) |
| Orthostatic hypotension | 0 | 1 (<0.1) | 1 (<0.1) |
| Pallor | 0 | 1 (<0.1) | 1 (<0.1) |
| Peripheral artery occlusion | 0 | 1 (<0.1) | 1 (<0.1) |
| Peripheral coldness | 0 | 1 (<0.1) | 1 (<0.1) |
| Accelerated hypertension | 1 (<0.1) | 0 | 1 (<0.1) |
| Aortic stenosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Fibromuscular dysplasia | 1 (<0.1) | 0 | 1 (<0.1) |
| Hypertensive emergency | 2 (<0.1) | 0 | 2 (<0.1) |
| Peripheral vascular disorder | 1 (<0.1) | 0 | 1 (<0.1) |

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Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Vascular disorders (Cont.) | | | |
| Phlebitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Thrombophlebitis superficial | 1 (<0.1) | 0 | 1 (<0.1) |
| Vasodilatation | 1 (<0.1) | 0 | 1 (<0.1) |
| Respiratory, thoracic and mediastinal disorders | 522 (3.4) | 480 (3.2) | 1002 (3.3) |
| Cough | 143 (0.9) | 148 (1.0) | 291 (1.0) |
| Oropharyngeal pain | 184 (1.2) | 137 (0.9) | 321 (1.1) |
| Nasal congestion | 119 (0.8) | 125 (0.8) | 244 (0.8) |
| Rhinorrhoea | 121 (0.8) | 118 (0.8) | 239 (0.8) |
| Dyspnoea | 35 (0.2) | 42 (0.3) | 77 (0.3) |
| Tachypnoea | 32 (0.2) | 35 (0.2) | 67 (0.2) |
| Throat irritation | 12 (<0.1) | 15 (<0.1) | 27 (<0.1) |
| Epistaxis | 9 (<0.1) | 14 (<0.1) | 23 (<0.1) |
| Sinus congestion | 25 (0.2) | 12 (<0.1) | 37 (0.1) |
| Asthma | 10 (<0.1) | 11 (<0.1) | 21 (<0.1) |
| Upper-airway cough syndrome | 7 (<0.1) | 10 (<0.1) | 17 (<0.1) |
| Sneezing | 10 (<0.1) | 8 (<0.1) | 18 (<0.1) |
| Respiratory tract congestion | 8 (<0.1) | 7 (<0.1) | 15 (<0.1) |
| Rhinitis allergic | 9 (<0.1) | 7 (<0.1) | 16 (<0.1) |
| Chronic obstructive pulmonary disease | 8 (<0.1) | 6 (<0.1) | 14 (<0.1) |
| Productive cough | 6 (<0.1) | 5 (<0.1) | 11 (<0.1) |
| Dry throat | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Dysphonia | 7 (<0.1) | 4 (<0.1) | 11 (<0.1) |
| Dyspnoea exertional | 1 (<0.1) | 4 (<0.1) | 5 (<0.1) |

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Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Respiratory, thoracic and mediastinal disorders (Cont.) | | | |
| Paranasal sinus discomfort | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Sinus pain | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Wheezing | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Pharyngeal erythema | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Pulmonary embolism | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Acute respiratory failure | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Allergic sinusitis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Atelectasis | 0 | 1 (<0.1) | 1 (<0.1) |
| Bronchiectasis | 0 | 1 (<0.1) | 1 (<0.1) |
| Bronchospasm | 0 | 1 (<0.1) | 1 (<0.1) |
| Increased viscosity of upper respiratory secretion | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Nasal discomfort | 0 | 1 (<0.1) | 1 (<0.1) |
| Nasal dryness | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Oropharyngeal discomfort | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Paranasal sinus hypersecretion | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Pleurisy | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Pleuritic pain | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Respiratory disorder | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Sleep apnoea syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Tonsillolith | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Vocal cord disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Laryngeal oedema | 1 (<0.1) | 0 | 1 (<0.1) |
| Nasal septum deviation | 1 (<0.1) | 0 | 1 (<0.1) |

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Respiratory, thoracic and mediastinal disorders (Cont.) | | | |
| Pharyngeal paraesthesia | 1 (<0.1) | 0 | 1 (<0.1) |
| Pleural effusion | 3 (<0.1) | 0 | 3 (<0.1) |
| Pneumonia aspiration | 1 (<0.1) | 0 | 1 (<0.1) |
| Pneumonitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Pulmonary congestion | 1 (<0.1) | 0 | 1 (<0.1) |
| Pulmonary mass | 1 (<0.1) | 0 | 1 (<0.1) |
| Respiratory symptom | 2 (<0.1) | 0 | 2 (<0.1) |
| Sinus polyp | 1 (<0.1) | 0 | 1 (<0.1) |
| Tonsillar exudate | 1 (<0.1) | 0 | 1 (<0.1) |
| Tonsillar hypertrophy | 1 (<0.1) | 0 | 1 (<0.1) |
| Tonsillar inflammation | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastrointestinal disorders | 387 (2.6) | 426 (2.8) | 813 (2.7) |
| Diarrhoea | 147 (1.0) | 178 (1.2) | 325 (1.1) |
| Nausea | 107 (0.7) | 103 (0.7) | 210 (0.7) |
| Vomiting | 32 (0.2) | 36 (0.2) | 68 (0.2) |
| Gastrooesophageal reflux disease | 11 (<0.1) | 29 (0.2) | 40 (0.1) |
| Toothache | 19 (0.1) | 26 (0.2) | 45 (0.1) |
| Abdominal pain | 15 (<0.1) | 17 (0.1) | 32 (0.1) |
| Abdominal pain upper | 14 (<0.1) | 10 (<0.1) | 24 (<0.1) |
| Constipation | 12 (<0.1) | 10 (<0.1) | 22 (<0.1) |
| Food poisoning | 6 (<0.1) | 10 (<0.1) | 16 (<0.1) |
| Dyspepsia | 11 (<0.1) | 8 (<0.1) | 19 (<0.1) |

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Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Gastrointestinal disorders (Cont.) | | | |
| Dental caries | 6 (<0.1) | 7 (<0.1) | 13 (<0.1) |
| Abdominal discomfort | 5 (<0.1) | 6 (<0.1) | 11 (<0.1) |
| Abdominal pain lower | 6 (<0.1) | 6 (<0.1) | 12 (<0.1) |
| Colitis | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Aphthous ulcer | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Gastric ulcer | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Haematochezia | 0 | 3 (<0.1) | 3 (<0.1) |
| Haemorrhoids | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Hyperaesthesia teeth | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Inguinal hernia | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Abdominal distension | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Anal fissure | 0 | 2 (<0.1) | 2 (<0.1) |
| Chapped lips | 0 | 2 (<0.1) | 2 (<0.1) |
| Dry mouth | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Lip swelling | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Mouth ulceration | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Oesophagitis | 0 | 2 (<0.1) | 2 (<0.1) |
| Proctalgia | 0 | 2 (<0.1) | 2 (<0.1) |
| Stomatitis | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Swollen tongue | 0 | 2 (<0.1) | 2 (<0.1) |
| Abdominal hernia | 0 | 1 (<0.1) | 1 (<0.1) |
| Diabetic gastroparesis | 0 | 1 (<0.1) | 1 (<0.1) |
| Diverticulum | 0 | 1 (<0.1) | 1 (<0.1) |
| Duodenal ulcer | 0 | 1 (<0.1) | 1 (<0.1) |

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Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Gastrointestinal disorders (Cont.) | | | |
| Enteritis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Flatulence | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Gastric disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Gingival bleeding | 0 | 1 (<0.1) | 1 (<0.1) |
| Hiatus hernia | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Hyperchlorhydria | 0 | 1 (<0.1) | 1 (<0.1) |
| Hypoaesthesia oral | 0 | 1 (<0.1) | 1 (<0.1) |
| Impaired gastric emptying | 0 | 1 (<0.1) | 1 (<0.1) |
| Irritable bowel syndrome | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Large intestine perforation | 0 | 1 (<0.1) | 1 (<0.1) |
| Oesophageal pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Oesophageal ulcer | 0 | 1 (<0.1) | 1 (<0.1) |
| Pancreatitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Pancreatitis acute | 0 | 1 (<0.1) | 1 (<0.1) |
| Paraesthesia oral | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Peptic ulcer | 0 | 1 (<0.1) | 1 (<0.1) |
| Proctitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Rectal haemorrhage | 0 | 1 (<0.1) | 1 (<0.1) |
| Salivary gland calculus | 0 | 1 (<0.1) | 1 (<0.1) |
| Salivary hypersecretion | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Small intestinal obstruction | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Submaxillary gland enlargement | 0 | 1 (<0.1) | 1 (<0.1) |
| Tongue discolouration | 0 | 1 (<0.1) | 1 (<0.1) |
| Tongue discomfort | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |

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|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Gastrointestinal disorders (Cont.) | | | |
| Tooth discolouration | 0 | 1 (<0.1) | 1 (<0.1) |
| Tooth impacted | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Umbilical hernia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Volvulus | 0 | 1 (<0.1) | 1 (<0.1) |
| Duodenal ulcer haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Dysphagia | 2 (<0.1) | 0 | 2 (<0.1) |
| Femoral hernia | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastric polyps | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastritis | 2 (<0.1) | 0 | 2 (<0.1) |
| Gastrointestinal haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastrointestinal motility disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastrointestinal pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Gingival discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Gingival pain | 3 (<0.1) | 0 | 3 (<0.1) |
| Glossitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Glossodynia | 1 (<0.1) | 0 | 1 (<0.1) |
| Intestinal obstruction | 1 (<0.1) | 0 | 1 (<0.1) |
| Large intestine polyp | 2 (<0.1) | 0 | 2 (<0.1) |
| Loose tooth | 1 (<0.1) | 0 | 1 (<0.1) |
| Oral discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Oral disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Oral pain | 4 (<0.1) | 0 | 4 (<0.1) |
| Palatal oedema | 1 (<0.1) | 0 | 1 (<0.1) |
| Regurgitation | 1 (<0.1) | 0 | 1 (<0.1) |

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Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Gastrointestinal disorders (Cont.) | | | |
| Retching | 1 (<0.1) | 0 | 1 (<0.1) |
| Saliva altered | 1 (<0.1) | 0 | 1 (<0.1) |
| Tongue coated | 1 (<0.1) | 0 | 1 (<0.1) |
| Tooth disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Hepatobiliary disorders | 1 (<0.1) | 10 (<0.1) | 11 (<0.1) |
| Cholelithiasis | 1 (<0.1) | 6 (<0.1) | 7 (<0.1) |
| Bile duct stone | 0 | 1 (<0.1) | 1 (<0.1) |
| Cholecystitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Cholecystitis acute | 0 | 1 (<0.1) | 1 (<0.1) |
| Hepatic mass | 0 | 1 (<0.1) | 1 (<0.1) |
| Skin and subcutaneous tissue disorders | 158 (1.0) | 213 (1.4) | 371 (1.2) |
| Rash | 26 (0.2) | 40 (0.3) | 66 (0.2) |
| Pruritus | 16 (0.1) | 20 (0.1) | 36 (0.1) |
| Urticaria | 12 (<0.1) | 18 (0.1) | 30 (<0.1) |
| Dermatitis contact | 23 (0.2) | 15 (<0.1) | 38 (0.1) |
| Hyperhidrosis | 10 (<0.1) | 12 (<0.1) | 22 (<0.1) |
| Erythema | 4 (<0.1) | 11 (<0.1) | 15 (<0.1) |
| Night sweats | 7 (<0.1) | 9 (<0.1) | 16 (<0.1) |
| Acne | 1 (<0.1) | 7 (<0.1) | 8 (<0.1) |
| Dermatitis | 4 (<0.1) | 7 (<0.1) | 11 (<0.1) |
| Alopecia | 3 (<0.1) | 6 (<0.1) | 9 (<0.1) |
| Rash erythematous | 2 (<0.1) | 6 (<0.1) | 8 (<0.1) |

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|--|-------------------------------|---------------------------------|-----------------------------|
| Skin and subcutaneous tissue disorders (Cont.) | | | |
| Ecchymosis | 4 (<0.1) | 5 (<0.1) | 9 (<0.1) |
| Pityriasis rosea | 0 | 4 (<0.1) | 4 (<0.1) |
| Rash pruritic | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Actinic keratosis | 0 | 3 (<0.1) | 3 (<0.1) |
| Blister | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Dermatitis atopic | 4 (<0.1) | 3 (<0.1) | 7 (<0.1) |
| Eczema | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Psoriasis | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Rosacea | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Skin burning sensation | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Skin lesion | 4 (<0.1) | 3 (<0.1) | 7 (<0.1) |
| Dermatitis allergic | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Hand dermatitis | 0 | 2 (<0.1) | 2 (<0.1) |
| Macule | 0 | 2 (<0.1) | 2 (<0.1) |
| Neurodermatitis | 0 | 2 (<0.1) | 2 (<0.1) |
| Rash papular | 0 | 2 (<0.1) | 2 (<0.1) |
| Urticaria papular | 4 (<0.1) | 2 (<0.1) | 6 (<0.1) |
| Angioedema | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Cold sweat | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Dermal cyst | 4 (<0.1) | 1 (<0.1) | 5 (<0.1) |
| Dry skin | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Exfoliative rash | 0 | 1 (<0.1) | 1 (<0.1) |
| Hidradenitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Ingrowing nail | 0 | 1 (<0.1) | 1 (<0.1) |

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Safety Set

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|--|-------------------------------|---------------------------------|-----------------------------|
| Skin and subcutaneous tissue disorders (Cont.) | | | |
| Lichen planus | 0 | 1 (<0.1) | 1 (<0.1) |
| Nail disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Pain of skin | 0 | 1 (<0.1) | 1 (<0.1) |
| Papule | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Petechiae | 0 | 1 (<0.1) | 1 (<0.1) |
| Rash maculo-papular | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Skin haemorrhage | 0 | 1 (<0.1) | 1 (<0.1) |
| Skin mass | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Skin warm | 0 | 1 (<0.1) | 1 (<0.1) |
| Solar lentigo | 0 | 1 (<0.1) | 1 (<0.1) |
| Dermatitis bullous | 2 (<0.1) | 0 | 2 (<0.1) |
| Idiopathic urticaria | 1 (<0.1) | 0 | 1 (<0.1) |
| Ingrown hair | 1 (<0.1) | 0 | 1 (<0.1) |
| Intertrigo | 1 (<0.1) | 0 | 1 (<0.1) |
| Lichenoid keratosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Livedo reticularis | 1 (<0.1) | 0 | 1 (<0.1) |
| Onychoclasia | 1 (<0.1) | 0 | 1 (<0.1) |
| Rash macular | 1 (<0.1) | 0 | 1 (<0.1) |
| Scab | 1 (<0.1) | 0 | 1 (<0.1) |
| Seborrheic dermatitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Skin discolouration | 2 (<0.1) | 0 | 2 (<0.1) |
| Skin hyperpigmentation | 1 (<0.1) | 0 | 1 (<0.1) |
| Skin irritation | 1 (<0.1) | 0 | 1 (<0.1) |
| Telangiectasia | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Skin and subcutaneous tissue disorders (Cont.) | | | |
| Umbilical erythema | 1 (<0.1) | 0 | 1 (<0.1) |
| Musculoskeletal and connective tissue disorders | 521 (3.4) | 586 (3.9) | 1107 (3.6) |
| Arthralgia | 152 (1.0) | 174 (1.1) | 326 (1.1) |
| Myalgia | 138 (0.9) | 172 (1.1) | 310 (1.0) |
| Back pain | 88 (0.6) | 73 (0.5) | 161 (0.5) |
| Pain in extremity | 59 (0.4) | 51 (0.3) | 110 (0.4) |
| Neck pain | 24 (0.2) | 34 (0.2) | 58 (0.2) |
| Musculoskeletal pain | 25 (0.2) | 31 (0.2) | 56 (0.2) |
| Muscle spasms | 11 (<0.1) | 26 (0.2) | 37 (0.1) |
| Tendonitis | 9 (<0.1) | 14 (<0.1) | 23 (<0.1) |
| Musculoskeletal chest pain | 10 (<0.1) | 10 (<0.1) | 20 (<0.1) |
| Musculoskeletal stiffness | 10 (<0.1) | 10 (<0.1) | 20 (<0.1) |
| Rotator cuff syndrome | 5 (<0.1) | 7 (<0.1) | 12 (<0.1) |
| Arthritis | 1 (<0.1) | 6 (<0.1) | 7 (<0.1) |
| Intervertebral disc protrusion | 2 (<0.1) | 5 (<0.1) | 7 (<0.1) |
| Joint swelling | 6 (<0.1) | 5 (<0.1) | 11 (<0.1) |
| Osteoarthritis | 11 (<0.1) | 5 (<0.1) | 16 (<0.1) |
| Bursitis | 4 (<0.1) | 4 (<0.1) | 8 (<0.1) |
| Groin pain | 1 (<0.1) | 4 (<0.1) | 5 (<0.1) |
| Limb discomfort | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |
| Pain in jaw | 4 (<0.1) | 4 (<0.1) | 8 (<0.1) |
| Bone pain | 0 | 3 (<0.1) | 3 (<0.1) |
| Costochondritis | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |

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Table 14.3.1.8.1
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Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Musculoskeletal and connective tissue disorders (Cont.) | | | |
| Flank pain | 0 | 3 (<0.1) | 3 (<0.1) |
| Joint range of motion decreased | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Muscular weakness | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Neck mass | 0 | 3 (<0.1) | 3 (<0.1) |
| Osteoporosis | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Axillary mass | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Exostosis | 0 | 2 (<0.1) | 2 (<0.1) |
| Fibromyalgia | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Joint stiffness | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Muscle tightness | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Plantar fasciitis | 4 (<0.1) | 2 (<0.1) | 6 (<0.1) |
| Spinal osteoarthritis | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Spinal pain | 0 | 2 (<0.1) | 2 (<0.1) |
| Spinal stenosis | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Trigger finger | 0 | 2 (<0.1) | 2 (<0.1) |
| Arthropathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Bone lesion | 0 | 1 (<0.1) | 1 (<0.1) |
| Bone swelling | 0 | 1 (<0.1) | 1 (<0.1) |
| Floating patella | 0 | 1 (<0.1) | 1 (<0.1) |
| Intervertebral disc degeneration | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Muscle fatigue | 0 | 1 (<0.1) | 1 (<0.1) |
| Muscle twitching | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Osteopenia | 0 | 1 (<0.1) | 1 (<0.1) |

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Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Musculoskeletal and connective tissue disorders (Cont.) | | | |
| Periarthritis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Polyarthritis | 0 | 1 (<0.1) | 1 (<0.1) |
| Rheumatoid arthritis | 0 | 1 (<0.1) | 1 (<0.1) |
| Spondylitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Spondylolysis | 0 | 1 (<0.1) | 1 (<0.1) |
| Temporomandibular joint syndrome | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Tendon disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Torticollis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Femoroacetabular impingement | 1 (<0.1) | 0 | 1 (<0.1) |
| Foot deformity | 1 (<0.1) | 0 | 1 (<0.1) |
| Intervertebral disc disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Limb mass | 1 (<0.1) | 0 | 1 (<0.1) |
| Musculoskeletal discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Myositis | 1 (<0.1) | 0 | 1 (<0.1) |
| Osteitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Polymyalgia rheumatica | 1 (<0.1) | 0 | 1 (<0.1) |
| Synovial cyst | 1 (<0.1) | 0 | 1 (<0.1) |
| Vertebral foraminal stenosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Renal and urinary disorders | 38 (0.3) | 35 (0.2) | 73 (0.2) |
| Nephrolithiasis | 21 (0.1) | 13 (<0.1) | 34 (0.1) |
| Dysuria | 1 (<0.1) | 5 (<0.1) | 6 (<0.1) |
| Haematuria | 6 (<0.1) | 2 (<0.1) | 8 (<0.1) |

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Renal and urinary disorders (Cont.) | | | |
| Polyuria | 0 | 2 (<0.1) | 2 (<0.1) |
| Urinary hesitation | 0 | 2 (<0.1) | 2 (<0.1) |
| Acute kidney injury | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Bladder pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Chronic kidney disease | 0 | 1 (<0.1) | 1 (<0.1) |
| Cystitis interstitial | 0 | 1 (<0.1) | 1 (<0.1) |
| End stage renal disease | 0 | 1 (<0.1) | 1 (<0.1) |
| Hydronephrosis | 0 | 1 (<0.1) | 1 (<0.1) |
| Lower urinary tract symptoms | 0 | 1 (<0.1) | 1 (<0.1) |
| Nocturia | 0 | 1 (<0.1) | 1 (<0.1) |
| Pollakiuria | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Renal pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Ureterolithiasis | 0 | 1 (<0.1) | 1 (<0.1) |
| Urinary incontinence | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Urinary retention | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Bladder prolapse | 1 (<0.1) | 0 | 1 (<0.1) |
| Chromaturia | 1 (<0.1) | 0 | 1 (<0.1) |
| Micturition urgency | 1 (<0.1) | 0 | 1 (<0.1) |
| Renal colic | 2 (<0.1) | 0 | 2 (<0.1) |
| Renal mass | 1 (<0.1) | 0 | 1 (<0.1) |
| Urge incontinence | 1 (<0.1) | 0 | 1 (<0.1) |
| Pregnancy, puerperium and perinatal conditions | 0 | 1 (<0.1) | 1 (<0.1) |
| Pregnancy | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Reproductive system and breast disorders | 30 (0.2) | 41 (0.3) | 71 (0.2) |
| Benign prostatic hyperplasia | 4 (<0.1) | 5 (<0.1) | 9 (<0.1) |
| Dysmenorrhoea | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |
| Erectile dysfunction | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Pelvic pain | 0 | 4 (<0.1) | 4 (<0.1) |
| Menorrhagia | 0 | 2 (<0.1) | 2 (<0.1) |
| Adenomyosis | 0 | 1 (<0.1) | 1 (<0.1) |
| Balanoposthitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Breast cyst | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Breast discharge | 0 | 1 (<0.1) | 1 (<0.1) |
| Breast disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Breast mass | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Breast pain | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Breast swelling | 0 | 1 (<0.1) | 1 (<0.1) |
| Cervical dysplasia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Dysfunctional uterine bleeding | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Menopausal symptoms | 0 | 1 (<0.1) | 1 (<0.1) |
| Menstrual disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Metrorrhagia | 0 | 1 (<0.1) | 1 (<0.1) |
| Nipple exudate bloody | 0 | 1 (<0.1) | 1 (<0.1) |
| Ovarian cyst | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Ovarian mass | 0 | 1 (<0.1) | 1 (<0.1) |
| Prostatitis | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Testicular pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Uterine haemorrhage | 0 | 1 (<0.1) | 1 (<0.1) |

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Safety Set

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|--|-------------------------------|---------------------------------|-----------------------------|
| Reproductive system and breast disorders (Cont.) | | | |
| Uterine polyp | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaginal discharge | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaginal haemorrhage | 0 | 1 (<0.1) | 1 (<0.1) |
| Vulvovaginal pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Amenorrhoea | 1 (<0.1) | 0 | 1 (<0.1) |
| Bartholin's cyst | 1 (<0.1) | 0 | 1 (<0.1) |
| Cystocele | 1 (<0.1) | 0 | 1 (<0.1) |
| Endometriosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Menstruation irregular | 1 (<0.1) | 0 | 1 (<0.1) |
| Oligomenorrhoea | 1 (<0.1) | 0 | 1 (<0.1) |
| Ovarian cyst ruptured | 2 (<0.1) | 0 | 2 (<0.1) |
| Polycystic ovaries | 1 (<0.1) | 0 | 1 (<0.1) |
| Prostatomegaly | 1 (<0.1) | 0 | 1 (<0.1) |
| Uterine cyst | 1 (<0.1) | 0 | 1 (<0.1) |
| Uterine spasm | 2 (<0.1) | 0 | 2 (<0.1) |
| Congenital, familial and genetic disorders | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Arnold-Chiari malformation | 0 | 1 (<0.1) | 1 (<0.1) |
| Dermoid cyst | 0 | 1 (<0.1) | 1 (<0.1) |
| Hydrocele | 1 (<0.1) | 0 | 1 (<0.1) |
| General disorders and administration site conditions | 560 (3.7) | 894 (5.9) | 1454 (4.8) |
| Fatigue | 307 (2.0) | 344 (2.3) | 651 (2.1) |

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Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| General disorders and administration site conditions (Cont.) | | | |
| Injection site pain | 49 (0.3) | 147 (1.0) | 196 (0.6) |
| Injection site erythema | 13 (<0.1) | 102 (0.7) | 115 (0.4) |
| Chills | 60 (0.4) | 77 (0.5) | 137 (0.5) |
| Injection site pruritus | 12 (<0.1) | 68 (0.4) | 80 (0.3) |
| Injection site swelling | 12 (<0.1) | 67 (0.4) | 79 (0.3) |
| Pyrexia | 39 (0.3) | 62 (0.4) | 101 (0.3) |
| Pain | 44 (0.3) | 57 (0.4) | 101 (0.3) |
| Injection site induration | 7 (<0.1) | 30 (0.2) | 37 (0.1) |
| Injection site rash | 1 (<0.1) | 30 (0.2) | 31 (0.1) |
| Axillary pain | 9 (<0.1) | 23 (0.2) | 32 (0.1) |
| Injection site bruising | 17 (0.1) | 12 (<0.1) | 29 (<0.1) |
| Malaise | 9 (<0.1) | 12 (<0.1) | 21 (<0.1) |
| Swelling | 4 (<0.1) | 11 (<0.1) | 15 (<0.1) |
| Chest discomfort | 9 (<0.1) | 10 (<0.1) | 19 (<0.1) |
| Chest pain | 9 (<0.1) | 10 (<0.1) | 19 (<0.1) |
| Injection site warmth | 1 (<0.1) | 8 (<0.1) | 9 (<0.1) |
| Injection site urticaria | 0 | 7 (<0.1) | 7 (<0.1) |
| Injection site lymphadenopathy | 1 (<0.1) | 6 (<0.1) | 7 (<0.1) |
| Oedema peripheral | 4 (<0.1) | 6 (<0.1) | 10 (<0.1) |
| Feeling hot | 3 (<0.1) | 5 (<0.1) | 8 (<0.1) |
| Injection site haemorrhage | 2 (<0.1) | 5 (<0.1) | 7 (<0.1) |
| Peripheral swelling | 9 (<0.1) | 5 (<0.1) | 14 (<0.1) |
| Reactogenicity event | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |

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Safety Set

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|--|-------------------------------|---------------------------------|-----------------------------|
| General disorders and administration site conditions (Cont.) | | | |
| Tenderness | 0 | 4 (<0.1) | 4 (<0.1) |
| Vaccination site lymphadenopathy | 0 | 4 (<0.1) | 4 (<0.1) |
| Influenza like illness | 4 (<0.1) | 3 (<0.1) | 7 (<0.1) |
| Injection site haematoma | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Injection site reaction | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Non-cardiac chest pain | 4 (<0.1) | 3 (<0.1) | 7 (<0.1) |
| Swelling face | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Vaccination site erythema | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Vaccination site swelling | 0 | 3 (<0.1) | 3 (<0.1) |
| Exercise tolerance decreased | 0 | 2 (<0.1) | 2 (<0.1) |
| Feeling abnormal | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Induration | 0 | 2 (<0.1) | 2 (<0.1) |
| Injection site irritation | 0 | 2 (<0.1) | 2 (<0.1) |
| Injection site joint pain | 0 | 2 (<0.1) | 2 (<0.1) |
| Injection site nodule | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Injection site paraesthesia | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Injection site scab | 0 | 2 (<0.1) | 2 (<0.1) |
| Vaccination site pain | 4 (<0.1) | 2 (<0.1) | 6 (<0.1) |
| Adverse drug reaction | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Asthenia | 4 (<0.1) | 1 (<0.1) | 5 (<0.1) |
| Crying | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Cyst | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Facial discomfort | 0 | 1 (<0.1) | 1 (<0.1) |

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|--|-------------------------------|---------------------------------|-----------------------------|
| General disorders and administration site conditions (Cont.) | | | |
| Facial pain | 4 (<0.1) | 1 (<0.1) | 5 (<0.1) |
| Feeling cold | 0 | 1 (<0.1) | 1 (<0.1) |
| Granuloma | 0 | 1 (<0.1) | 1 (<0.1) |
| Inflammation | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site hypoaesthesia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Injection site mass | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Injury associated with device | 0 | 1 (<0.1) | 1 (<0.1) |
| Nodule | 0 | 1 (<0.1) | 1 (<0.1) |
| Sensation of foreign body | 0 | 1 (<0.1) | 1 (<0.1) |
| Temperature intolerance | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaccination site induration | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaccination site pruritus | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Vaccination site rash | 0 | 1 (<0.1) | 1 (<0.1) |
| Vessel puncture site haematoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Vessel puncture site haemorrhage | 0 | 1 (<0.1) | 1 (<0.1) |
| Discomfort | 2 (<0.1) | 0 | 2 (<0.1) |
| Gait disturbance | 1 (<0.1) | 0 | 1 (<0.1) |
| Hangover | 1 (<0.1) | 0 | 1 (<0.1) |
| Hunger | 1 (<0.1) | 0 | 1 (<0.1) |
| Incarcerated hernia | 1 (<0.1) | 0 | 1 (<0.1) |
| Injection site discolouration | 2 (<0.1) | 0 | 2 (<0.1) |
| Injection site discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Pelvic mass | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| General disorders and administration site conditions (Cont.) | | | |
| Polyp | 1 (<0.1) | 0 | 1 (<0.1) |
| Precancerous condition | 2 (<0.1) | 0 | 2 (<0.1) |
| Thirst | 1 (<0.1) | 0 | 1 (<0.1) |
| Vaccination site bruising | 2 (<0.1) | 0 | 2 (<0.1) |
| Vaccination site inflammation | 1 (<0.1) | 0 | 1 (<0.1) |
| Vaccination site nodule | 1 (<0.1) | 0 | 1 (<0.1) |
| Vessel puncture site bruise | 1 (<0.1) | 0 | 1 (<0.1) |
| Xerosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Investigations | 59 (0.4) | 82 (0.5) | 141 (0.5) |
| Blood pressure increased | 22 (0.1) | 23 (0.2) | 45 (0.1) |
| Blood pressure systolic increased | 10 (<0.1) | 15 (<0.1) | 25 (<0.1) |
| Blood pressure diastolic increased | 2 (<0.1) | 8 (<0.1) | 10 (<0.1) |
| Heart rate increased | 1 (<0.1) | 4 (<0.1) | 5 (<0.1) |
| Body temperature increased | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Hepatic enzyme increased | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Blood glucose increased | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Blood triglycerides increased | 0 | 2 (<0.1) | 2 (<0.1) |
| Hormone level abnormal | 0 | 2 (<0.1) | 2 (<0.1) |
| Transaminases increased | 0 | 2 (<0.1) | 2 (<0.1) |
| Aspartate aminotransferase increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Blood cholesterol increased | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Blood creatine increased | 0 | 1 (<0.1) | 1 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Investigations (Cont.) | | | |
| Blood creatinine increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Blood glucose decreased | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Blood parathyroid hormone increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Blood pressure systolic decreased | 0 | 1 (<0.1) | 1 (<0.1) |
| Blood testosterone decreased | 0 | 1 (<0.1) | 1 (<0.1) |
| Body temperature decreased | 0 | 1 (<0.1) | 1 (<0.1) |
| Cardiac murmur | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Electrocardiogram T wave inversion | 0 | 1 (<0.1) | 1 (<0.1) |
| Fibrin D dimer increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Glycosylated haemoglobin increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Heart rate irregular | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Hepatic enzyme abnormal | 0 | 1 (<0.1) | 1 (<0.1) |
| Influenza A virus test positive | 0 | 1 (<0.1) | 1 (<0.1) |
| Mammogram abnormal | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Neutrophil count increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Oxygen saturation decreased | 0 | 1 (<0.1) | 1 (<0.1) |
| Prostatic specific antigen increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Respiratory rate increased | 0 | 1 (<0.1) | 1 (<0.1) |
| SARS-CoV-2 test positive | 4 (<0.1) | 1 (<0.1) | 5 (<0.1) |
| Thyroid function test abnormal | 0 | 1 (<0.1) | 1 (<0.1) |
| Urine transitional cells present | 0 | 1 (<0.1) | 1 (<0.1) |
| Weight decreased | 0 | 1 (<0.1) | 1 (<0.1) |
| White blood cell count increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Alanine aminotransferase increased | 1 (<0.1) | 0 | 1 (<0.1) |

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MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403010801.sas 18NOV2020 06:18

Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Investigations (Cont.) | | | |
| Biopsy skin | 1 (<0.1) | 0 | 1 (<0.1) |
| Blood iron decreased | 2 (<0.1) | 0 | 2 (<0.1) |
| Blood potassium decreased | 1 (<0.1) | 0 | 1 (<0.1) |
| Brain natriuretic peptide increased | 1 (<0.1) | 0 | 1 (<0.1) |
| C-reactive protein increased | 1 (<0.1) | 0 | 1 (<0.1) |
| Colonoscopy | 1 (<0.1) | 0 | 1 (<0.1) |
| Lipase increased | 1 (<0.1) | 0 | 1 (<0.1) |
| Vitamin B12 decreased | 1 (<0.1) | 0 | 1 (<0.1) |
| Vitamin D decreased | 2 (<0.1) | 0 | 2 (<0.1) |
| Weight increased | 1 (<0.1) | 0 | 1 (<0.1) |
| Injury, poisoning and procedural complications | 262 (1.7) | 238 (1.6) | 500 (1.6) |
| Muscle strain | 24 (0.2) | 31 (0.2) | 55 (0.2) |
| Ligament sprain | 23 (0.2) | 21 (0.1) | 44 (0.1) |
| Skin laceration | 25 (0.2) | 20 (0.1) | 45 (0.1) |
| Arthropod bite | 21 (0.1) | 19 (0.1) | 40 (0.1) |
| Contusion | 26 (0.2) | 14 (<0.1) | 40 (0.1) |
| Fall | 13 (<0.1) | 11 (<0.1) | 24 (<0.1) |
| Limb injury | 5 (<0.1) | 10 (<0.1) | 15 (<0.1) |
| Tooth fracture | 12 (<0.1) | 10 (<0.1) | 22 (<0.1) |
| Foot fracture | 8 (<0.1) | 9 (<0.1) | 17 (<0.1) |
| Procedural pain | 11 (<0.1) | 8 (<0.1) | 19 (<0.1) |
| Arthropod sting | 13 (<0.1) | 7 (<0.1) | 20 (<0.1) |
| Road traffic accident | 3 (<0.1) | 6 (<0.1) | 9 (<0.1) |

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Injury, poisoning and procedural complications (Cont.) | | | |
| Skin abrasion | 17 (0.1) | 6 (<0.1) | 23 (<0.1) |
| Animal bite | 7 (<0.1) | 5 (<0.1) | 12 (<0.1) |
| Concussion | 3 (<0.1) | 5 (<0.1) | 8 (<0.1) |
| Hand fracture | 1 (<0.1) | 5 (<0.1) | 6 (<0.1) |
| Meniscus injury | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |
| Epicondylitis | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Joint injury | 4 (<0.1) | 3 (<0.1) | 7 (<0.1) |
| Rib fracture | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Back injury | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Cartilage injury | 0 | 2 (<0.1) | 2 (<0.1) |
| Cervical vertebral fracture | 0 | 2 (<0.1) | 2 (<0.1) |
| Facial bones fracture | 0 | 2 (<0.1) | 2 (<0.1) |
| Head injury | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Heat exhaustion | 0 | 2 (<0.1) | 2 (<0.1) |
| Ligament rupture | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Muscle rupture | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Tendon injury | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Tendon rupture | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Thermal burn | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Upper limb fracture | 0 | 2 (<0.1) | 2 (<0.1) |
| Wrist fracture | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Alcohol poisoning | 0 | 1 (<0.1) | 1 (<0.1) |
| Animal scratch | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Injury, poisoning and procedural complications (Cont.) | | | |
| Ankle fracture | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Bone fragmentation | 0 | 1 (<0.1) | 1 (<0.1) |
| Burns first degree | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Burns second degree | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Clavicle fracture | 0 | 1 (<0.1) | 1 (<0.1) |
| Corneal abrasion | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Craniocerebral injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Exposure to SARS-CoV-2 | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Face injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Femoral neck fracture | 0 | 1 (<0.1) | 1 (<0.1) |
| Fibula fracture | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Hip fracture | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Hypobarism | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection related reaction | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Joint dislocation | 0 | 1 (<0.1) | 1 (<0.1) |
| Ligament injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Lower limb fracture | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Lumbar vertebral fracture | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Meniscus cyst | 0 | 1 (<0.1) | 1 (<0.1) |
| Nasal injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Overdose | 0 | 1 (<0.1) | 1 (<0.1) |
| Patella fracture | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Injury, poisoning and procedural complications (Cont.) | | | |
| Periorbital haematoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Periorbital haemorrhage | 0 | 1 (<0.1) | 1 (<0.1) |
| Post procedural haemorrhage | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Post-traumatic neck syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Post-traumatic pain | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Procedural headache | 0 | 1 (<0.1) | 1 (<0.1) |
| Respiratory fume inhalation disorder | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Scar | 0 | 1 (<0.1) | 1 (<0.1) |
| Scratch | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Subdural haematoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Tibia fracture | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Tooth injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Traumatic liver injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaccination complication | 0 | 1 (<0.1) | 1 (<0.1) |
| Wound | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Abdominal injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Bone contusion | 2 (<0.1) | 0 | 2 (<0.1) |
| Exposure to toxic agent | 1 (<0.1) | 0 | 1 (<0.1) |
| Eye injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Eyelid contusion | 1 (<0.1) | 0 | 1 (<0.1) |
| Foreign body | 2 (<0.1) | 0 | 2 (<0.1) |
| Foreign body in ear | 1 (<0.1) | 0 | 1 (<0.1) |
| Humerus fracture | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Injury, poisoning and procedural complications (Cont.) | | | |
| Iliotibial band syndrome | 1 (<0.1) | 0 | 1 (<0.1) |
| Immunisation anxiety related reaction | 1 (<0.1) | 0 | 1 (<0.1) |
| Lip injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Mouth injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Muscle injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Nail injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Post procedural haematoma | 1 (<0.1) | 0 | 1 (<0.1) |
| Procedural anxiety | 1 (<0.1) | 0 | 1 (<0.1) |
| Procedural haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Procedural nausea | 1 (<0.1) | 0 | 1 (<0.1) |
| Sports injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Stress fracture | 3 (<0.1) | 0 | 3 (<0.1) |
| Sunburn | 1 (<0.1) | 0 | 1 (<0.1) |
| Superficial injury of eye | 1 (<0.1) | 0 | 1 (<0.1) |
| Ulna fracture | 1 (<0.1) | 0 | 1 (<0.1) |
| Ulnar nerve injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Venomous sting | 1 (<0.1) | 0 | 1 (<0.1) |
| Surgical and medical procedures | 10 (<0.1) | 15 (<0.1) | 25 (<0.1) |
| Axillary lymphadenectomy | 0 | 2 (<0.1) | 2 (<0.1) |
| Endodontic procedure | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Ankle arthroplasty | 0 | 1 (<0.1) | 1 (<0.1) |
| Cholecystectomy | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Surgical and medical procedures (Cont.) | | | |
| Curettage of chalazion | 0 | 1 (<0.1) | 1 (<0.1) |
| Cyst removal | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Dental operation | 0 | 1 (<0.1) | 1 (<0.1) |
| Lipoma excision | 0 | 1 (<0.1) | 1 (<0.1) |
| Phlebectomy | 0 | 1 (<0.1) | 1 (<0.1) |
| Skin neoplasm excision | 0 | 1 (<0.1) | 1 (<0.1) |
| Skin operation | 0 | 1 (<0.1) | 1 (<0.1) |
| Thyroidectomy | 0 | 1 (<0.1) | 1 (<0.1) |
| Transurethral prostatectomy | 0 | 1 (<0.1) | 1 (<0.1) |
| Carpal tunnel decompression | 1 (<0.1) | 0 | 1 (<0.1) |
| Cataract operation | 1 (<0.1) | 0 | 1 (<0.1) |
| Fracture treatment | 1 (<0.1) | 0 | 1 (<0.1) |
| Hip arthroplasty | 1 (<0.1) | 0 | 1 (<0.1) |
| Tooth extraction | 1 (<0.1) | 0 | 1 (<0.1) |
| Tooth repair | 2 (<0.1) | 0 | 2 (<0.1) |
| Umbilical hernia repair | 1 (<0.1) | 0 | 1 (<0.1) |
| Social circumstances | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Menopause | 0 | 1 (<0.1) | 1 (<0.1) |
| Sexual abuse | 1 (<0.1) | 0 | 1 (<0.1) |
| Product issues | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Device breakage | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Device dislocation | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Product issues (Cont.) | | | |
| Embedded device | 0 | 1 (<0.1) | 1 (<0.1) |
| Lead dislodgement | 1 (<0.1) | 0 | 1 (<0.1) |
| Uncoded | 153 (1.0) | 244 (1.6) | 397 (1.3) |
| Uncoded | 153 (1.0) | 244 (1.6) | 397 (1.3) |

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Number of Subjects Reporting Unsolicited Adverse Events | 2215 (19.4) | 2453 (21.5) | 4668 (20.4) |
| Number of Unsolicited Adverse Events | 4051 | 4554 | 8605 |
| Infections and infestations | 481 (4.2) | 406 (3.6) | 887 (3.9) |
| Urinary tract infection | 54 (0.5) | 53 (0.5) | 107 (0.5) |
| Sinusitis | 23 (0.2) | 43 (0.4) | 66 (0.3) |
| Upper respiratory tract infection | 57 (0.5) | 36 (0.3) | 93 (0.4) |
| Viral infection | 27 (0.2) | 19 (0.2) | 46 (0.2) |
| COVID-19 | 94 (0.8) | 15 (0.1) | 109 (0.5) |
| Herpes zoster | 7 (<0.1) | 12 (0.1) | 19 (<0.1) |
| Pharyngitis | 18 (0.2) | 12 (0.1) | 30 (0.1) |
| Tooth abscess | 12 (0.1) | 12 (0.1) | 24 (0.1) |
| Tooth infection | 9 (<0.1) | 12 (0.1) | 21 (<0.1) |
| Ear infection | 5 (<0.1) | 11 (<0.1) | 16 (<0.1) |
| Gastroenteritis | 11 (<0.1) | 11 (<0.1) | 22 (<0.1) |
| Pharyngitis streptococcal | 14 (0.1) | 11 (<0.1) | 25 (0.1) |
| Rhinovirus infection | 4 (<0.1) | 11 (<0.1) | 15 (<0.1) |
| Conjunctivitis | 4 (<0.1) | 9 (<0.1) | 13 (<0.1) |
| Cellulitis | 6 (<0.1) | 8 (<0.1) | 14 (<0.1) |
| Oral herpes | 4 (<0.1) | 6 (<0.1) | 10 (<0.1) |
| Bacterial vaginosis | 5 (<0.1) | 5 (<0.1) | 10 (<0.1) |
| Fungal infection | 6 (<0.1) | 5 (<0.1) | 11 (<0.1) |
| Hordeolum | 7 (<0.1) | 5 (<0.1) | 12 (<0.1) |

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Infections and infestations (Cont.) | | | |
| Otitis media | 6 (<0.1) | 5 (<0.1) | 11 (<0.1) |
| Viral upper respiratory tract infection | 8 (<0.1) | 5 (<0.1) | 13 (<0.1) |
| Acute sinusitis | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Diverticulitis | 4 (<0.1) | 4 (<0.1) | 8 (<0.1) |
| Folliculitis | 1 (<0.1) | 4 (<0.1) | 5 (<0.1) |
| Gingivitis | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |
| Pneumonia | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Respiratory tract infection | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |
| Vulvovaginal candidiasis | 1 (<0.1) | 4 (<0.1) | 5 (<0.1) |
| Abscess limb | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Asymptomatic COVID-19 | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Helicobacter infection | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Herpes simplex | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Injection site cellulitis | 0 | 3 (<0.1) | 3 (<0.1) |
| Nasopharyngitis | 7 (<0.1) | 3 (<0.1) | 10 (<0.1) |
| Paronychia | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Rhinitis | 5 (<0.1) | 3 (<0.1) | 8 (<0.1) |
| Skin infection | 0 | 3 (<0.1) | 3 (<0.1) |
| Vulvovaginal mycotic infection | 8 (<0.1) | 3 (<0.1) | 11 (<0.1) |
| Bronchitis | 5 (<0.1) | 2 (<0.1) | 7 (<0.1) |
| Chlamydial infection | 0 | 2 (<0.1) | 2 (<0.1) |
| Clostridium difficile infection | 0 | 2 (<0.1) | 2 (<0.1) |
| Impetigo | 0 | 2 (<0.1) | 2 (<0.1) |
| Kidney infection | 0 | 2 (<0.1) | 2 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Infections and infestations (Cont.) | | | |
| Localised infection | 5 (<0.1) | 2 (<0.1) | 7 (<0.1) |
| Lyme disease | 0 | 2 (<0.1) | 2 (<0.1) |
| Onychomycosis | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Oral candidiasis | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Otitis externa | 7 (<0.1) | 2 (<0.1) | 9 (<0.1) |
| Soft tissue infection | 0 | 2 (<0.1) | 2 (<0.1) |
| Staphylococcal skin infection | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Subcutaneous abscess | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Tonsillitis | 7 (<0.1) | 2 (<0.1) | 9 (<0.1) |
| Upper respiratory tract infection bacterial | 0 | 2 (<0.1) | 2 (<0.1) |
| Viral rhinitis | 0 | 2 (<0.1) | 2 (<0.1) |
| Abscess jaw | 0 | 1 (<0.1) | 1 (<0.1) |
| Bacterial infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Body tinea | 0 | 1 (<0.1) | 1 (<0.1) |
| Candida infection | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Cat scratch disease | 0 | 1 (<0.1) | 1 (<0.1) |
| Catheter site infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Chronic sinusitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Clostridium difficile colitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Conjunctivitis bacterial | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Enterovirus infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Epididymitis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Furuncle | 0 | 1 (<0.1) | 1 (<0.1) |
| Gastroenteritis viral | 6 (<0.1) | 1 (<0.1) | 7 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class | Placebo (N=11415) | mRNA-1273 (N=11414) | Total (N=22830) |
|-------------------------------------|----------------------|------------------------|--------------------|
| Preferred Term | n (%) | n (%) | n (%) |
| Infections and infestations (Cont.) | | | |
| Genital herpes | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Gonorrhoea | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Hepatitis A | 0 | 1 (<0.1) | 1 (<0.1) |
| Infected bite | 0 | 1 (<0.1) | 1 (<0.1) |
| Infected cyst | 0 | 1 (<0.1) | 1 (<0.1) |
| Large intestine infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Laryngitis viral | 0 | 1 (<0.1) | 1 (<0.1) |
| Osteomyelitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Otitis media acute | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Parainfluenzae virus infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Parotitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Periodontitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Pharyngitis bacterial | 0 | 1 (<0.1) | 1 (<0.1) |
| Proctitis chlamydial | 0 | 1 (<0.1) | 1 (<0.1) |
| Respiratory tract infection viral | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Rocky mountain spotted fever | 0 | 1 (<0.1) | 1 (<0.1) |
| Sexually transmitted disease | 0 | 1 (<0.1) | 1 (<0.1) |
| Staphylococcal infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Tinea pedis | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Toxic shock syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Viral pharyngitis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Wound infection | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Appendicitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Breast abscess | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class | Placebo (N=11415) | mRNA-1273 (N=11414) | Total (N=22830) |
|-------------------------------------|----------------------|------------------------|--------------------|
| Preferred Term | n (%) | n (%) | n (%) |
| Infections and infestations (Cont.) | | | |
| Breast cellulitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Campylobacter infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Corneal infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Cystitis | 5 (<0.1) | 0 | 5 (<0.1) |
| Eye infection | 4 (<0.1) | 0 | 4 (<0.1) |
| Gardnerella infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastrointestinal viral infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Herpes virus infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Influenza | 1 (<0.1) | 0 | 1 (<0.1) |
| Laryngitis | 2 (<0.1) | 0 | 2 (<0.1) |
| Latent tuberculosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Mastoiditis | 1 (<0.1) | 0 | 1 (<0.1) |
| Nasal abscess | 1 (<0.1) | 0 | 1 (<0.1) |
| Ophthalmic herpes zoster | 1 (<0.1) | 0 | 1 (<0.1) |
| Pelvic abscess | 1 (<0.1) | 0 | 1 (<0.1) |
| Post procedural infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Pustule | 1 (<0.1) | 0 | 1 (<0.1) |
| Pyelonephritis acute | 1 (<0.1) | 0 | 1 (<0.1) |
| Root canal infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Septic shock | 1 (<0.1) | 0 | 1 (<0.1) |
| Sialoadenitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Sinusitis bacterial | 1 (<0.1) | 0 | 1 (<0.1) |
| Skin candida | 1 (<0.1) | 0 | 1 (<0.1) |
| Streptococcal infection | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Infections and infestations (Cont.) | | | |
| Suspected COVID-19 | 2 (<0.1) | 0 | 2 (<0.1) |
| Syphilis | 1 (<0.1) | 0 | 1 (<0.1) |
| Tinea infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Tinea versicolour | 1 (<0.1) | 0 | 1 (<0.1) |
| Varicella zoster virus infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 10 (<0.1) | 18 (0.2) | 28 (0.1) |
| Basal cell carcinoma | 4 (<0.1) | 2 (<0.1) | 6 (<0.1) |
| Melanocytic naevus | 0 | 2 (<0.1) | 2 (<0.1) |
| Squamous cell carcinoma | 0 | 2 (<0.1) | 2 (<0.1) |
| Uterine leiomyoma | 0 | 2 (<0.1) | 2 (<0.1) |
| Breast neoplasm | 0 | 1 (<0.1) | 1 (<0.1) |
| Cutaneous lymphoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Haemangioma of liver | 0 | 1 (<0.1) | 1 (<0.1) |
| Lipoma of breast | 0 | 1 (<0.1) | 1 (<0.1) |
| Lung cancer metastatic | 0 | 1 (<0.1) | 1 (<0.1) |
| Malignant melanoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Malignant melanoma in situ | 0 | 1 (<0.1) | 1 (<0.1) |
| Pelvic neoplasm | 0 | 1 (<0.1) | 1 (<0.1) |
| Skin papilloma | 0 | 1 (<0.1) | 1 (<0.1) |
| Thyroid cancer | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Benign neoplasm of skin | 1 (<0.1) | 0 | 1 (<0.1) |
| Breast cancer | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.) | | | |
| Chondromatosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Prolactin-producing pituitary tumour | 1 (<0.1) | 0 | 1 (<0.1) |
| Squamous cell carcinoma of skin | 1 (<0.1) | 0 | 1 (<0.1) |
| Blood and lymphatic system disorders | 53 (0.5) | 92 (0.8) | 145 (0.6) |
| Lymphadenopathy | 46 (0.4) | 76 (0.7) | 122 (0.5) |
| Anaemia | 0 | 6 (<0.1) | 6 (<0.1) |
| Lymph node pain | 2 (<0.1) | 5 (<0.1) | 7 (<0.1) |
| Lymphadenitis | 0 | 5 (<0.1) | 5 (<0.1) |
| Iron deficiency anaemia | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Splenomegaly | 0 | 1 (<0.1) | 1 (<0.1) |
| Thrombocytopenia | 0 | 1 (<0.1) | 1 (<0.1) |
| Increased tendency to bruise | 1 (<0.1) | 0 | 1 (<0.1) |
| Leukocytosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Immune system disorders | 24 (0.2) | 20 (0.2) | 44 (0.2) |
| Seasonal allergy | 16 (0.1) | 13 (0.1) | 29 (0.1) |
| Hypersensitivity | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Allergy to arthropod bite | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Autoimmune disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Drug hypersensitivity | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Food allergy | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Allergy to plants | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Immune system disorders (Cont.) | | | |
| Anaphylactic reaction | 1 (<0.1) | 0 | 1 (<0.1) |
| Smoke sensitivity | 1 (<0.1) | 0 | 1 (<0.1) |
| Endocrine disorders | 4 (<0.1) | 5 (<0.1) | 9 (<0.1) |
| Hypothyroidism | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Thyroid cyst | 0 | 1 (<0.1) | 1 (<0.1) |
| Hypogonadism | 1 (<0.1) | 0 | 1 (<0.1) |
| Oestrogen deficiency | 1 (<0.1) | 0 | 1 (<0.1) |
| Metabolism and nutrition disorders | 50 (0.4) | 43 (0.4) | 93 (0.4) |
| Decreased appetite | 5 (<0.1) | 8 (<0.1) | 13 (<0.1) |
| Type 2 diabetes mellitus | 2 (<0.1) | 7 (<0.1) | 9 (<0.1) |
| Hyperlipidaemia | 7 (<0.1) | 5 (<0.1) | 12 (<0.1) |
| Vitamin D deficiency | 7 (<0.1) | 5 (<0.1) | 12 (<0.1) |
| Dehydration | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Hypercholesterolaemia | 10 (<0.1) | 3 (<0.1) | 13 (<0.1) |
| Hypertriglyceridaemia | 0 | 3 (<0.1) | 3 (<0.1) |
| Diabetes mellitus | 0 | 2 (<0.1) | 2 (<0.1) |
| Hyperglycaemia | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Abnormal loss of weight | 0 | 1 (<0.1) | 1 (<0.1) |
| Food intolerance | 0 | 1 (<0.1) | 1 (<0.1) |
| Glucose tolerance impaired | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Gluten sensitivity | 0 | 1 (<0.1) | 1 (<0.1) |
| Gout | 5 (<0.1) | 1 (<0.1) | 6 (<0.1) |

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Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Metabolism and nutrition disorders (Cont.) | | | |
| Hypoglycaemia | 0 | 1 (<0.1) | 1 (<0.1) |
| Hypokalaemia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Magnesium deficiency | 0 | 1 (<0.1) | 1 (<0.1) |
| Abnormal weight gain | 1 (<0.1) | 0 | 1 (<0.1) |
| Calcium deficiency | 1 (<0.1) | 0 | 1 (<0.1) |
| Dyslipidaemia | 1 (<0.1) | 0 | 1 (<0.1) |
| Folate deficiency | 1 (<0.1) | 0 | 1 (<0.1) |
| Increased appetite | 1 (<0.1) | 0 | 1 (<0.1) |
| Iron deficiency | 1 (<0.1) | 0 | 1 (<0.1) |
| Polydipsia | 1 (<0.1) | 0 | 1 (<0.1) |
| Vitamin B12 deficiency | 1 (<0.1) | 0 | 1 (<0.1) |
| Psychiatric disorders | 60 (0.5) | 71 (0.6) | 131 (0.6) |
| Depression | 15 (0.1) | 21 (0.2) | 36 (0.2) |
| Anxiety | 21 (0.2) | 18 (0.2) | 39 (0.2) |
| Insomnia | 10 (<0.1) | 11 (<0.1) | 21 (<0.1) |
| Abnormal dreams | 1 (<0.1) | 5 (<0.1) | 6 (<0.1) |
| Attention deficit hyperactivity disorder | 4 (<0.1) | 4 (<0.1) | 8 (<0.1) |
| Sleep disorder | 0 | 3 (<0.1) | 3 (<0.1) |
| Bipolar disorder | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Adjustment disorder with depressed mood | 0 | 1 (<0.1) | 1 (<0.1) |
| Affect lability | 0 | 1 (<0.1) | 1 (<0.1) |
| Alcohol withdrawal syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Anxiety disorder | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Psychiatric disorders (Cont.) | | | |
| Completed suicide | 0 | 1 (<0.1) | 1 (<0.1) |
| Libido decreased | 0 | 1 (<0.1) | 1 (<0.1) |
| Major depression | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Panic attack | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Post-traumatic stress disorder | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Schizoaffective disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Stress | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Substance abuse | 0 | 1 (<0.1) | 1 (<0.1) |
| Alcohol abuse | 1 (<0.1) | 0 | 1 (<0.1) |
| Generalised anxiety disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Mental fatigue | 1 (<0.1) | 0 | 1 (<0.1) |
| Mental status changes | 1 (<0.1) | 0 | 1 (<0.1) |
| Persistent depressive disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Psychotic disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Seasonal affective disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Suicidal ideation | 1 (<0.1) | 0 | 1 (<0.1) |
| Nervous system disorders | 439 (3.8) | 489 (4.3) | 928 (4.1) |
| Headache | 335 (2.9) | 346 (3.0) | 681 (3.0) |
| Dizziness | 30 (0.3) | 45 (0.4) | 75 (0.3) |
| Paraesthesia | 17 (0.1) | 20 (0.2) | 37 (0.2) |
| Dysgeusia | 3 (<0.1) | 9 (<0.1) | 12 (<0.1) |
| Migraine | 16 (0.1) | 9 (<0.1) | 25 (0.1) |
| Ageusia | 6 (<0.1) | 8 (<0.1) | 14 (<0.1) |

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Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class | Placebo (N=11415) | mRNA-1273 (N=11414) | Total (N=22830) |
|--------------------------------------|----------------------|------------------------|--------------------|
| Preferred Term | n (%) | n (%) | n (%) |
| Nervous system disorders (Cont.) | | | |
| Anosmia | 5 (<0.1) | 7 (<0.1) | 12 (<0.1) |
| Hypoaesthesia | 3 (<0.1) | 6 (<0.1) | 9 (<0.1) |
| Presyncope | 8 (<0.1) | 6 (<0.1) | 14 (<0.1) |
| Sciatica | 3 (<0.1) | 6 (<0.1) | 9 (<0.1) |
| Syncope | 7 (<0.1) | 6 (<0.1) | 13 (<0.1) |
| Tension headache | 2 (<0.1) | 6 (<0.1) | 8 (<0.1) |
| Sinus headache | 4 (<0.1) | 5 (<0.1) | 9 (<0.1) |
| Hyperaesthesia | 0 | 4 (<0.1) | 4 (<0.1) |
| Carpal tunnel syndrome | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Mental impairment | 0 | 3 (<0.1) | 3 (<0.1) |
| Burning sensation | 0 | 2 (<0.1) | 2 (<0.1) |
| Seizure | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Somnolence | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Carotid artery stenosis | 0 | 1 (<0.1) | 1 (<0.1) |
| Cubital tunnel syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Diabetic neuropathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Disturbance in attention | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Dizziness postural | 0 | 1 (<0.1) | 1 (<0.1) |
| Idiopathic intracranial hypertension | 0 | 1 (<0.1) | 1 (<0.1) |
| Lethargy | 0 | 1 (<0.1) | 1 (<0.1) |
| Memory impairment | 0 | 1 (<0.1) | 1 (<0.1) |
| Migraine with aura | 0 | 1 (<0.1) | 1 (<0.1) |
| Migraine without aura | 0 | 1 (<0.1) | 1 (<0.1) |
| Movement disorder | 0 | 1 (<0.1) | 1 (<0.1) |

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Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class | Placebo (N=11415) | mRNA-1273 (N=11414) | Total (N=22830) |
|--|----------------------|------------------------|--------------------|
| Preferred Term | n (%) | n (%) | n (%) |
| Nervous system disorders (Cont.) | | | |
| Nerve compression | 0 | 1 (<0.1) | 1 (<0.1) |
| Neuralgia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Neuropathy peripheral | 0 | 1 (<0.1) | 1 (<0.1) |
| Parosmia | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Peripheral sensory neuropathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Post-traumatic headache | 0 | 1 (<0.1) | 1 (<0.1) |
| Primary headache associated with sexual activity | 0 | 1 (<0.1) | 1 (<0.1) |
| Small fibre neuropathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Tardive dyskinesia | 0 | 1 (<0.1) | 1 (<0.1) |
| Taste disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Thoracic outlet syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Transient ischaemic attack | 0 | 1 (<0.1) | 1 (<0.1) |
| Visual field defect | 0 | 1 (<0.1) | 1 (<0.1) |
| Basal ganglia haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Dysaesthesia | 2 (<0.1) | 0 | 2 (<0.1) |
| Encephalitis autoimmune | 1 (<0.1) | 0 | 1 (<0.1) |
| Facial paralysis | 1 (<0.1) | 0 | 1 (<0.1) |
| Head discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Horner's syndrome | 1 (<0.1) | 0 | 1 (<0.1) |
| Hypogeusia | 2 (<0.1) | 0 | 2 (<0.1) |
| Hyposmia | 1 (<0.1) | 0 | 1 (<0.1) |
| Lumbar radiculopathy | 2 (<0.1) | 0 | 2 (<0.1) |
| Muscle contractions involuntary | 1 (<0.1) | 0 | 1 (<0.1) |
| Tarsal tunnel syndrome | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class | Placebo (N=11415) | mRNA-1273 (N=11414) | Total (N=22830) |
|--------------------------------------|----------------------|------------------------|--------------------|
| Preferred Term | n (%) | n (%) | n (%) |
| Eye disorders | 26 (0.2) | 31 (0.3) | 57 (0.2) |
| Eye pruritus | 3 (<0.1) | 5 (<0.1) | 8 (<0.1) |
| Eye irritation | 0 | 3 (<0.1) | 3 (<0.1) |
| Lacrimation increased | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Ocular hyperaemia | 5 (<0.1) | 2 (<0.1) | 7 (<0.1) |
| Vision blurred | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Blepharitis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Blepharospasm | 0 | 1 (<0.1) | 1 (<0.1) |
| Blindness transient | 0 | 1 (<0.1) | 1 (<0.1) |
| Conjunctival haemorrhage | 0 | 1 (<0.1) | 1 (<0.1) |
| Conjunctival hyperaemia | 0 | 1 (<0.1) | 1 (<0.1) |
| Dry age-related macular degeneration | 0 | 1 (<0.1) | 1 (<0.1) |
| Dry eye | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Eye discharge | 0 | 1 (<0.1) | 1 (<0.1) |
| Eye inflammation | 0 | 1 (<0.1) | 1 (<0.1) |
| Eye swelling | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Eyelid cyst | 0 | 1 (<0.1) | 1 (<0.1) |
| Iris disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Noninfective conjunctivitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Photophobia | 0 | 1 (<0.1) | 1 (<0.1) |
| Retinal detachment | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Swelling of eyelid | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Visual impairment | 0 | 1 (<0.1) | 1 (<0.1) |
| Vitreous floaters | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Xerophthalmia | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class | Placebo (N=11415) | mRNA-1273 (N=11414) | Total (N=22830) |
|-----------------------------|----------------------|------------------------|--------------------|
| Preferred Term | n (%) | n (%) | n (%) |
| Eye disorders (Cont.) | | | |
| Conjunctivitis allergic | 1 (<0.1) | 0 | 1 (<0.1) |
| Dacryoadenitis acquired | 1 (<0.1) | 0 | 1 (<0.1) |
| Eyelid ptosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Macular degeneration | 1 (<0.1) | 0 | 1 (<0.1) |
| Periorbital pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Periorbital swelling | 1 (<0.1) | 0 | 1 (<0.1) |
| Visual acuity reduced | 1 (<0.1) | 0 | 1 (<0.1) |
| Ear and labyrinth disorders | 39 (0.3) | 36 (0.3) | 75 (0.3) |
| Ear pain | 8 (<0.1) | 10 (<0.1) | 18 (<0.1) |
| Vertigo | 8 (<0.1) | 9 (<0.1) | 17 (<0.1) |
| Tinnitus | 7 (<0.1) | 6 (<0.1) | 13 (<0.1) |
| Vertigo positional | 0 | 3 (<0.1) | 3 (<0.1) |
| Ear canal erythema | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Ear discomfort | 4 (<0.1) | 2 (<0.1) | 6 (<0.1) |
| Cerumen impaction | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Deafness neurosensory | 0 | 1 (<0.1) | 1 (<0.1) |
| Eustachian tube dysfunction | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Middle ear effusion | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Motion sickness | 0 | 1 (<0.1) | 1 (<0.1) |
| Otorrhoea | 0 | 1 (<0.1) | 1 (<0.1) |
| Deafness | 1 (<0.1) | 0 | 1 (<0.1) |
| Ear congestion | 2 (<0.1) | 0 | 2 (<0.1) |
| Ear haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Ear and labyrinth disorders (Cont.) | | | |
| Ear pruritus | 1 (<0.1) | 0 | 1 (<0.1) |
| Tympanic membrane perforation | 3 (<0.1) | 0 | 3 (<0.1) |
| Cardiac disorders | 35 (0.3) | 30 (0.3) | 65 (0.3) |
| Tachycardia | 9 (<0.1) | 10 (<0.1) | 19 (<0.1) |
| Bradycardia | 11 (<0.1) | 9 (<0.1) | 20 (<0.1) |
| Myocardial infarction | 0 | 3 (<0.1) | 3 (<0.1) |
| Palpitations | 4 (<0.1) | 3 (<0.1) | 7 (<0.1) |
| Atrial fibrillation | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Cardiac failure | 0 | 1 (<0.1) | 1 (<0.1) |
| Cardiac failure congestive | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Chronic left ventricular failure | 0 | 1 (<0.1) | 1 (<0.1) |
| Sinus tachycardia | 0 | 1 (<0.1) | 1 (<0.1) |
| Ventricular extrasystoles | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Acute left ventricular failure | 1 (<0.1) | 0 | 1 (<0.1) |
| Angina pectoris | 1 (<0.1) | 0 | 1 (<0.1) |
| Arrhythmia | 2 (<0.1) | 0 | 2 (<0.1) |
| Atrial tachycardia | 1 (<0.1) | 0 | 1 (<0.1) |
| Cardiac flutter | 1 (<0.1) | 0 | 1 (<0.1) |
| Cardio-respiratory arrest | 1 (<0.1) | 0 | 1 (<0.1) |
| Cardiomyopathy | 1 (<0.1) | 0 | 1 (<0.1) |
| Vascular disorders | 87 (0.8) | 97 (0.8) | 184 (0.8) |
| Hypertension | 69 (0.6) | 78 (0.7) | 147 (0.6) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Vascular disorders (Cont.) | | | |
| Flushing | 2 (<0.1) | 5 (<0.1) | 7 (<0.1) |
| Hot flush | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |
| Haematoma | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Systolic hypertension | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Achenbach syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Deep vein thrombosis | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Hypertensive urgency | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Hypotension | 0 | 1 (<0.1) | 1 (<0.1) |
| Pallor | 0 | 1 (<0.1) | 1 (<0.1) |
| Peripheral coldness | 0 | 1 (<0.1) | 1 (<0.1) |
| Accelerated hypertension | 1 (<0.1) | 0 | 1 (<0.1) |
| Aortic aneurysm | 1 (<0.1) | 0 | 1 (<0.1) |
| Aortic stenosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Hypertensive emergency | 2 (<0.1) | 0 | 2 (<0.1) |
| Thrombophlebitis superficial | 1 (<0.1) | 0 | 1 (<0.1) |
| Respiratory, thoracic and mediastinal disorders | 416 (3.6) | 378 (3.3) | 794 (3.5) |
| Cough | 127 (1.1) | 124 (1.1) | 251 (1.1) |
| Oropharyngeal pain | 158 (1.4) | 112 (1.0) | 270 (1.2) |
| Nasal congestion | 96 (0.8) | 101 (0.9) | 197 (0.9) |
| Rhinorrhoea | 94 (0.8) | 84 (0.7) | 178 (0.8) |
| Dyspnoea | 29 (0.3) | 33 (0.3) | 62 (0.3) |
| Tachypnoea | 28 (0.2) | 31 (0.3) | 59 (0.3) |
| Throat irritation | 9 (<0.1) | 13 (0.1) | 22 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Respiratory, thoracic and mediastinal disorders (Cont.) | | | |
| Epistaxis | 4 (<0.1) | 11 (<0.1) | 15 (<0.1) |
| Sinus congestion | 20 (0.2) | 10 (<0.1) | 30 (0.1) |
| Asthma | 9 (<0.1) | 6 (<0.1) | 15 (<0.1) |
| Rhinitis allergic | 5 (<0.1) | 6 (<0.1) | 11 (<0.1) |
| Respiratory tract congestion | 8 (<0.1) | 5 (<0.1) | 13 (<0.1) |
| Upper-airway cough syndrome | 6 (<0.1) | 5 (<0.1) | 11 (<0.1) |
| Chronic obstructive pulmonary disease | 4 (<0.1) | 4 (<0.1) | 8 (<0.1) |
| Productive cough | 4 (<0.1) | 4 (<0.1) | 8 (<0.1) |
| Sneezing | 9 (<0.1) | 4 (<0.1) | 13 (<0.1) |
| Dry throat | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Dyspnoea exertional | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Paranasal sinus discomfort | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Pharyngeal erythema | 0 | 2 (<0.1) | 2 (<0.1) |
| Pulmonary embolism | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Sinus pain | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Wheezing | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Acute respiratory failure | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Allergic sinusitis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Atelectasis | 0 | 1 (<0.1) | 1 (<0.1) |
| Dysphonia | 5 (<0.1) | 1 (<0.1) | 6 (<0.1) |
| Increased viscosity of upper respiratory secretion | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Nasal discomfort | 0 | 1 (<0.1) | 1 (<0.1) |
| Nasal dryness | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Respiratory, thoracic and mediastinal disorders (Cont.) | | | |
| Oropharyngeal discomfort | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Paranasal sinus hypersecretion | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Pleurisy | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Pleuritic pain | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Tonsillolith | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Vocal cord disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Laryngeal oedema | 1 (<0.1) | 0 | 1 (<0.1) |
| Pharyngeal paraesthesia | 1 (<0.1) | 0 | 1 (<0.1) |
| Pleural effusion | 1 (<0.1) | 0 | 1 (<0.1) |
| Pneumonia aspiration | 1 (<0.1) | 0 | 1 (<0.1) |
| Pneumonitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Pulmonary mass | 1 (<0.1) | 0 | 1 (<0.1) |
| Respiratory disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Respiratory symptom | 2 (<0.1) | 0 | 2 (<0.1) |
| Sinus polyp | 1 (<0.1) | 0 | 1 (<0.1) |
| Tonsillar inflammation | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastrointestinal disorders | 288 (2.5) | 314 (2.8) | 602 (2.6) |
| Diarrhoea | 104 (0.9) | 138 (1.2) | 242 (1.1) |
| Nausea | 88 (0.8) | 74 (0.6) | 162 (0.7) |
| Vomiting | 25 (0.2) | 25 (0.2) | 50 (0.2) |
| Toothache | 15 (0.1) | 19 (0.2) | 34 (0.1) |
| Gastroesophageal reflux disease | 9 (<0.1) | 17 (0.1) | 26 (0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class | Placebo (N=11415) | mRNA-1273 (N=11414) | Total (N=22830) |
|------------------------------------|----------------------|------------------------|--------------------|
| Preferred Term | n (%) | n (%) | n (%) |
| Gastrointestinal disorders (Cont.) | | | |
| Abdominal pain | 13 (0.1) | 14 (0.1) | 27 (0.1) |
| Food poisoning | 4 (<0.1) | 9 (<0.1) | 13 (<0.1) |
| Constipation | 8 (<0.1) | 8 (<0.1) | 16 (<0.1) |
| Abdominal pain upper | 11 (<0.1) | 6 (<0.1) | 17 (<0.1) |
| Abdominal discomfort | 3 (<0.1) | 5 (<0.1) | 8 (<0.1) |
| Abdominal pain lower | 5 (<0.1) | 4 (<0.1) | 9 (<0.1) |
| Dental caries | 4 (<0.1) | 4 (<0.1) | 8 (<0.1) |
| Aphthous ulcer | 0 | 3 (<0.1) | 3 (<0.1) |
| Colitis | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Dyspepsia | 10 (<0.1) | 3 (<0.1) | 13 (<0.1) |
| Gastric ulcer | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Haematochezia | 0 | 3 (<0.1) | 3 (<0.1) |
| Haemorrhoids | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Abdominal distension | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Anal fissure | 0 | 2 (<0.1) | 2 (<0.1) |
| Chapped lips | 0 | 2 (<0.1) | 2 (<0.1) |
| Hyperaesthesia teeth | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Mouth ulceration | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Oesophagitis | 0 | 2 (<0.1) | 2 (<0.1) |
| Proctalgia | 0 | 2 (<0.1) | 2 (<0.1) |
| Abdominal hernia | 0 | 1 (<0.1) | 1 (<0.1) |
| Diabetic gastroparesis | 0 | 1 (<0.1) | 1 (<0.1) |
| Diverticulum | 0 | 1 (<0.1) | 1 (<0.1) |
| Dry mouth | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Gastrointestinal disorders (Cont.) | | | |
| Duodenal ulcer | 0 | 1 (<0.1) | 1 (<0.1) |
| Enteritis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Flatulence | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Gastric disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Gingival bleeding | 0 | 1 (<0.1) | 1 (<0.1) |
| Hyperchlorhydria | 0 | 1 (<0.1) | 1 (<0.1) |
| Impaired gastric emptying | 0 | 1 (<0.1) | 1 (<0.1) |
| Inguinal hernia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Irritable bowel syndrome | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Large intestine perforation | 0 | 1 (<0.1) | 1 (<0.1) |
| Lip swelling | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Oesophageal ulcer | 0 | 1 (<0.1) | 1 (<0.1) |
| Pancreatitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Peptic ulcer | 0 | 1 (<0.1) | 1 (<0.1) |
| Proctitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Small intestinal obstruction | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Stomatitis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Submaxillary gland enlargement | 0 | 1 (<0.1) | 1 (<0.1) |
| Swollen tongue | 0 | 1 (<0.1) | 1 (<0.1) |
| Tongue discolouration | 0 | 1 (<0.1) | 1 (<0.1) |
| Tongue discomfort | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Tooth impacted | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Umbilical hernia | 0 | 1 (<0.1) | 1 (<0.1) |
| Dysphagia | 2 (<0.1) | 0 | 2 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Gastrointestinal disorders (Cont.) | | | |
| Femoral hernia | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastric polyps | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastritis | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastrointestinal haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastrointestinal pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Gingival discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Gingival pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Glossitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Glossodynia | 1 (<0.1) | 0 | 1 (<0.1) |
| Hiatus hernia | 2 (<0.1) | 0 | 2 (<0.1) |
| Loose tooth | 1 (<0.1) | 0 | 1 (<0.1) |
| Oral disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Oral pain | 2 (<0.1) | 0 | 2 (<0.1) |
| Palatal oedema | 1 (<0.1) | 0 | 1 (<0.1) |
| Paraesthesia oral | 2 (<0.1) | 0 | 2 (<0.1) |
| Regurgitation | 1 (<0.1) | 0 | 1 (<0.1) |
| Saliva altered | 1 (<0.1) | 0 | 1 (<0.1) |
| Tongue coated | 1 (<0.1) | 0 | 1 (<0.1) |
| Tooth disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Hepatobiliary disorders | 1 (<0.1) | 7 (<0.1) | 8 (<0.1) |
| Cholelithiasis | 1 (<0.1) | 5 (<0.1) | 6 (<0.1) |
| Cholecystitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Hepatic mass | 0 | 1 (<0.1) | 1 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Skin and subcutaneous tissue disorders | 109 (1.0) | 150 (1.3) | 259 (1.1) |
| Rash | 22 (0.2) | 30 (0.3) | 52 (0.2) |
| Dermatitis contact | 13 (0.1) | 12 (0.1) | 25 (0.1) |
| Pruritus | 9 (<0.1) | 12 (0.1) | 21 (<0.1) |
| Urticaria | 9 (<0.1) | 12 (0.1) | 21 (<0.1) |
| Hyperhidrosis | 8 (<0.1) | 9 (<0.1) | 17 (<0.1) |
| Acne | 1 (<0.1) | 7 (<0.1) | 8 (<0.1) |
| Night sweats | 5 (<0.1) | 7 (<0.1) | 12 (<0.1) |
| Alopecia | 3 (<0.1) | 6 (<0.1) | 9 (<0.1) |
| Dermatitis | 3 (<0.1) | 5 (<0.1) | 8 (<0.1) |
| Rash erythematous | 2 (<0.1) | 5 (<0.1) | 7 (<0.1) |
| Ecchymosis | 1 (<0.1) | 4 (<0.1) | 5 (<0.1) |
| Erythema | 1 (<0.1) | 4 (<0.1) | 5 (<0.1) |
| Blister | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Pityriasis rosea | 0 | 3 (<0.1) | 3 (<0.1) |
| Psoriasis | 0 | 3 (<0.1) | 3 (<0.1) |
| Skin burning sensation | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Dermatitis allergic | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Eczema | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Hand dermatitis | 0 | 2 (<0.1) | 2 (<0.1) |
| Rash pruritic | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Skin lesion | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Urticaria papular | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Angioedema | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Cold sweat | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Skin and subcutaneous tissue disorders (Cont.) | | | |
| Dermal cyst | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Dry skin | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Exfoliative rash | 0 | 1 (<0.1) | 1 (<0.1) |
| Hidradenitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Lichen planus | 0 | 1 (<0.1) | 1 (<0.1) |
| Macule | 0 | 1 (<0.1) | 1 (<0.1) |
| Pain of skin | 0 | 1 (<0.1) | 1 (<0.1) |
| Papule | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Petechiae | 0 | 1 (<0.1) | 1 (<0.1) |
| Rash maculo-papular | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Rash papular | 0 | 1 (<0.1) | 1 (<0.1) |
| Rosacea | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Skin haemorrhage | 0 | 1 (<0.1) | 1 (<0.1) |
| Skin warm | 0 | 1 (<0.1) | 1 (<0.1) |
| Dermatitis atopic | 4 (<0.1) | 0 | 4 (<0.1) |
| Dermatitis bullous | 1 (<0.1) | 0 | 1 (<0.1) |
| Idiopathic urticaria | 1 (<0.1) | 0 | 1 (<0.1) |
| Ingrown hair | 1 (<0.1) | 0 | 1 (<0.1) |
| Intertrigo | 1 (<0.1) | 0 | 1 (<0.1) |
| Livedo reticularis | 1 (<0.1) | 0 | 1 (<0.1) |
| Onychoclasia | 1 (<0.1) | 0 | 1 (<0.1) |
| Rash macular | 1 (<0.1) | 0 | 1 (<0.1) |
| Skin discolouration | 2 (<0.1) | 0 | 2 (<0.1) |
| Skin hyperpigmentation | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Skin and subcutaneous tissue disorders (Cont.) | | | |
| Skin irritation | 1 (<0.1) | 0 | 1 (<0.1) |
| Umbilical erythema | 1 (<0.1) | 0 | 1 (<0.1) |
| Musculoskeletal and connective tissue disorders | 378 (3.3) | 422 (3.7) | 800 (3.5) |
| Myalgia | 108 (0.9) | 131 (1.1) | 239 (1.0) |
| Arthralgia | 111 (1.0) | 123 (1.1) | 234 (1.0) |
| Back pain | 63 (0.6) | 52 (0.5) | 115 (0.5) |
| Pain in extremity | 42 (0.4) | 37 (0.3) | 79 (0.3) |
| Neck pain | 17 (0.1) | 25 (0.2) | 42 (0.2) |
| Musculoskeletal pain | 20 (0.2) | 22 (0.2) | 42 (0.2) |
| Muscle spasms | 6 (<0.1) | 18 (0.2) | 24 (0.1) |
| Tendonitis | 5 (<0.1) | 10 (<0.1) | 15 (<0.1) |
| Musculoskeletal chest pain | 9 (<0.1) | 9 (<0.1) | 18 (<0.1) |
| Intervertebral disc protrusion | 2 (<0.1) | 5 (<0.1) | 7 (<0.1) |
| Rotator cuff syndrome | 2 (<0.1) | 5 (<0.1) | 7 (<0.1) |
| Groin pain | 0 | 4 (<0.1) | 4 (<0.1) |
| Musculoskeletal stiffness | 9 (<0.1) | 4 (<0.1) | 13 (<0.1) |
| Osteoarthritis | 4 (<0.1) | 4 (<0.1) | 8 (<0.1) |
| Pain in jaw | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Arthritis | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Bone pain | 0 | 3 (<0.1) | 3 (<0.1) |
| Bursitis | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Limb discomfort | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Axillary mass | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class | Placebo (N=11415) | mRNA-1273 (N=11414) | Total (N=22830) |
|--|----------------------|------------------------|--------------------|
| Preferred Term | n (%) | n (%) | n (%) |
| Musculoskeletal and connective tissue disorders (Cont.) | | | |
| Costochondritis | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Exostosis | 0 | 2 (<0.1) | 2 (<0.1) |
| Fibromyalgia | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Flank pain | 0 | 2 (<0.1) | 2 (<0.1) |
| Joint range of motion decreased | 0 | 2 (<0.1) | 2 (<0.1) |
| Joint swelling | 6 (<0.1) | 2 (<0.1) | 8 (<0.1) |
| Neck mass | 0 | 2 (<0.1) | 2 (<0.1) |
| Plantar fasciitis | 4 (<0.1) | 2 (<0.1) | 6 (<0.1) |
| Spinal pain | 0 | 2 (<0.1) | 2 (<0.1) |
| Arthropathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Bone lesion | 0 | 1 (<0.1) | 1 (<0.1) |
| Bone swelling | 0 | 1 (<0.1) | 1 (<0.1) |
| Floating patella | 0 | 1 (<0.1) | 1 (<0.1) |
| Intervertebral disc degeneration | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Joint stiffness | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Muscle tightness | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Muscle twitching | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Muscular weakness | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Osteopenia | 0 | 1 (<0.1) | 1 (<0.1) |
| Polyarthrititis | 0 | 1 (<0.1) | 1 (<0.1) |
| Rheumatoid arthritis | 0 | 1 (<0.1) | 1 (<0.1) |
| Spinal osteoarthritis | 0 | 1 (<0.1) | 1 (<0.1) |
| Spondylolysis | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Musculoskeletal and connective tissue disorders (Cont.) | | | |
| Temporomandibular joint syndrome | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Torticollis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Femoroacetabular impingement | 1 (<0.1) | 0 | 1 (<0.1) |
| Intervertebral disc disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Limb mass | 1 (<0.1) | 0 | 1 (<0.1) |
| Musculoskeletal discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Myositis | 1 (<0.1) | 0 | 1 (<0.1) |
| Osteitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Spinal stenosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Synovial cyst | 1 (<0.1) | 0 | 1 (<0.1) |
| Vertebral foraminal stenosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Renal and urinary disorders | 20 (0.2) | 19 (0.2) | 39 (0.2) |
| Nephrolithiasis | 14 (0.1) | 7 (<0.1) | 21 (<0.1) |
| Dysuria | 1 (<0.1) | 4 (<0.1) | 5 (<0.1) |
| Acute kidney injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Bladder pain | 0 | 1 (<0.1) | 1 (<0.1) |
| End stage renal disease | 0 | 1 (<0.1) | 1 (<0.1) |
| Hydronephrosis | 0 | 1 (<0.1) | 1 (<0.1) |
| Nocturia | 0 | 1 (<0.1) | 1 (<0.1) |
| Polyuria | 0 | 1 (<0.1) | 1 (<0.1) |
| Renal pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Ureterolithiasis | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class | Placebo (N=11415) | mRNA-1273 (N=11414) | Total (N=22830) |
|--|----------------------|------------------------|--------------------|
| Preferred Term | n (%) | n (%) | n (%) |
| Renal and urinary disorders (Cont.) | | | |
| Urinary hesitation | 0 | 1 (<0.1) | 1 (<0.1) |
| Urinary incontinence | 0 | 1 (<0.1) | 1 (<0.1) |
| Bladder prolapse | 1 (<0.1) | 0 | 1 (<0.1) |
| Haematuria | 4 (<0.1) | 0 | 4 (<0.1) |
| Renal colic | 1 (<0.1) | 0 | 1 (<0.1) |
| Urinary retention | 1 (<0.1) | 0 | 1 (<0.1) |
| Pregnancy, puerperium and perinatal conditions | 0 | 1 (<0.1) | 1 (<0.1) |
| Pregnancy | 0 | 1 (<0.1) | 1 (<0.1) |
| Reproductive system and breast disorders | 27 (0.2) | 28 (0.2) | 55 (0.2) |
| Dysmenorrhoea | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |
| Pelvic pain | 0 | 4 (<0.1) | 4 (<0.1) |
| Erectile dysfunction | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Menorrhagia | 0 | 2 (<0.1) | 2 (<0.1) |
| Breast cyst | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Breast disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Breast pain | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Cervical dysplasia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Dysfunctional uterine bleeding | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Menopausal symptoms | 0 | 1 (<0.1) | 1 (<0.1) |
| Menstrual disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Metrorrhagia | 0 | 1 (<0.1) | 1 (<0.1) |
| Nipple exudate bloody | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class | Placebo (N=11415) | mRNA-1273 (N=11414) | Total (N=22830) |
|--|----------------------|------------------------|--------------------|
| Preferred Term | n (%) | n (%) | n (%) |
| Reproductive system and breast disorders (Cont.) | | | |
| Ovarian mass | 0 | 1 (<0.1) | 1 (<0.1) |
| Prostatitis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Testicular pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Uterine haemorrhage | 0 | 1 (<0.1) | 1 (<0.1) |
| Uterine polyp | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaginal discharge | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaginal haemorrhage | 0 | 1 (<0.1) | 1 (<0.1) |
| Vulvovaginal pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Amenorrhoea | 1 (<0.1) | 0 | 1 (<0.1) |
| Bartholin's cyst | 1 (<0.1) | 0 | 1 (<0.1) |
| Benign prostatic hyperplasia | 3 (<0.1) | 0 | 3 (<0.1) |
| Breast mass | 1 (<0.1) | 0 | 1 (<0.1) |
| Cystocele | 1 (<0.1) | 0 | 1 (<0.1) |
| Endometriosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Menstruation irregular | 1 (<0.1) | 0 | 1 (<0.1) |
| Oligomenorrhoea | 1 (<0.1) | 0 | 1 (<0.1) |
| Ovarian cyst | 1 (<0.1) | 0 | 1 (<0.1) |
| Ovarian cyst ruptured | 2 (<0.1) | 0 | 2 (<0.1) |
| Polycystic ovaries | 1 (<0.1) | 0 | 1 (<0.1) |
| Uterine cyst | 1 (<0.1) | 0 | 1 (<0.1) |
| Uterine spasm | 2 (<0.1) | 0 | 2 (<0.1) |
| Congenital, familial and genetic disorders | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Arnold-Chiari malformation | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Congenital, familial and genetic disorders (Cont.) | | | |
| Dermoid cyst | 0 | 1 (<0.1) | 1 (<0.1) |
| Hydrocele | 1 (<0.1) | 0 | 1 (<0.1) |
| General disorders and administration site conditions | 432 (3.8) | 680 (6.0) | 1112 (4.9) |
| Fatigue | 249 (2.2) | 252 (2.2) | 501 (2.2) |
| Injection site pain | 36 (0.3) | 119 (1.0) | 155 (0.7) |
| Injection site erythema | 6 (<0.1) | 70 (0.6) | 76 (0.3) |
| Chills | 47 (0.4) | 61 (0.5) | 108 (0.5) |
| Injection site swelling | 7 (<0.1) | 55 (0.5) | 62 (0.3) |
| Injection site pruritus | 10 (<0.1) | 50 (0.4) | 60 (0.3) |
| Pyrexia | 35 (0.3) | 49 (0.4) | 84 (0.4) |
| Pain | 34 (0.3) | 45 (0.4) | 79 (0.3) |
| Injection site induration | 4 (<0.1) | 26 (0.2) | 30 (0.1) |
| Injection site rash | 1 (<0.1) | 22 (0.2) | 23 (0.1) |
| Axillary pain | 7 (<0.1) | 20 (0.2) | 27 (0.1) |
| Malaise | 4 (<0.1) | 11 (<0.1) | 15 (<0.1) |
| Swelling | 3 (<0.1) | 10 (<0.1) | 13 (<0.1) |
| Chest discomfort | 7 (<0.1) | 9 (<0.1) | 16 (<0.1) |
| Chest pain | 7 (<0.1) | 9 (<0.1) | 16 (<0.1) |
| Injection site bruising | 11 (<0.1) | 9 (<0.1) | 20 (<0.1) |
| Injection site urticaria | 0 | 6 (<0.1) | 6 (<0.1) |
| Injection site warmth | 1 (<0.1) | 6 (<0.1) | 7 (<0.1) |
| Injection site lymphadenopathy | 1 (<0.1) | 5 (<0.1) | 6 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| General disorders and administration site conditions (Cont.) | | | |
| Feeling hot | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |
| Injection site haemorrhage | 1 (<0.1) | 4 (<0.1) | 5 (<0.1) |
| Tenderness | 0 | 4 (<0.1) | 4 (<0.1) |
| Influenza like illness | 4 (<0.1) | 3 (<0.1) | 7 (<0.1) |
| Injection site haematoma | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Non-cardiac chest pain | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Oedema peripheral | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Peripheral swelling | 5 (<0.1) | 3 (<0.1) | 8 (<0.1) |
| Reactogenicity event | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Swelling face | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Vaccination site erythema | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Vaccination site lymphadenopathy | 0 | 3 (<0.1) | 3 (<0.1) |
| Vaccination site swelling | 0 | 3 (<0.1) | 3 (<0.1) |
| Induration | 0 | 2 (<0.1) | 2 (<0.1) |
| Injection site irritation | 0 | 2 (<0.1) | 2 (<0.1) |
| Injection site nodule | 0 | 2 (<0.1) | 2 (<0.1) |
| Injection site reaction | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Adverse drug reaction | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Crying | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Cyst | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Exercise tolerance decreased | 0 | 1 (<0.1) | 1 (<0.1) |
| Facial discomfort | 0 | 1 (<0.1) | 1 (<0.1) |
| Facial pain | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |

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Table 14.3.1.8.4
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| General disorders and administration site conditions (Cont.) | | | |
| Feeling abnormal | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Feeling cold | 0 | 1 (<0.1) | 1 (<0.1) |
| Granuloma | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site hypoaesthesia | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site joint pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site mass | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site paraesthesia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Injection site scab | 0 | 1 (<0.1) | 1 (<0.1) |
| Injury associated with device | 0 | 1 (<0.1) | 1 (<0.1) |
| Nodule | 0 | 1 (<0.1) | 1 (<0.1) |
| Sensation of foreign body | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaccination site induration | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaccination site pruritus | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Vaccination site rash | 0 | 1 (<0.1) | 1 (<0.1) |
| Vessel puncture site haematoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Asthenia | 3 (<0.1) | 0 | 3 (<0.1) |
| Discomfort | 2 (<0.1) | 0 | 2 (<0.1) |
| Hangover | 1 (<0.1) | 0 | 1 (<0.1) |
| Hunger | 1 (<0.1) | 0 | 1 (<0.1) |
| Injection site discolouration | 1 (<0.1) | 0 | 1 (<0.1) |
| Injection site discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Polyp | 1 (<0.1) | 0 | 1 (<0.1) |
| Precancerous condition | 2 (<0.1) | 0 | 2 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| General disorders and administration site conditions (Cont.) | | | |
| Vaccination site bruising | 2 (<0.1) | 0 | 2 (<0.1) |
| Vaccination site nodule | 1 (<0.1) | 0 | 1 (<0.1) |
| Vaccination site pain | 4 (<0.1) | 0 | 4 (<0.1) |
| Xerosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Investigations | 44 (0.4) | 52 (0.5) | 96 (0.4) |
| Blood pressure increased | 16 (0.1) | 13 (0.1) | 29 (0.1) |
| Blood pressure systolic increased | 6 (<0.1) | 9 (<0.1) | 15 (<0.1) |
| Blood pressure diastolic increased | 2 (<0.1) | 6 (<0.1) | 8 (<0.1) |
| Body temperature increased | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Heart rate increased | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Hepatic enzyme increased | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Blood triglycerides increased | 0 | 2 (<0.1) | 2 (<0.1) |
| Hormone level abnormal | 0 | 2 (<0.1) | 2 (<0.1) |
| Transaminases increased | 0 | 2 (<0.1) | 2 (<0.1) |
| Aspartate aminotransferase increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Blood cholesterol increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Blood glucose increased | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Blood testosterone decreased | 0 | 1 (<0.1) | 1 (<0.1) |
| Electrocardiogram T wave inversion | 0 | 1 (<0.1) | 1 (<0.1) |
| Fibrin D dimer increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Heart rate irregular | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Hepatic enzyme abnormal | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Investigations (Cont.) | | | |
| Influenza A virus test positive | 0 | 1 (<0.1) | 1 (<0.1) |
| Mammogram abnormal | 0 | 1 (<0.1) | 1 (<0.1) |
| Oxygen saturation decreased | 0 | 1 (<0.1) | 1 (<0.1) |
| Respiratory rate increased | 0 | 1 (<0.1) | 1 (<0.1) |
| SARS-CoV-2 test positive | 4 (<0.1) | 1 (<0.1) | 5 (<0.1) |
| Thyroid function test abnormal | 0 | 1 (<0.1) | 1 (<0.1) |
| Urine transitional cells present | 0 | 1 (<0.1) | 1 (<0.1) |
| White blood cell count increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Alanine aminotransferase increased | 1 (<0.1) | 0 | 1 (<0.1) |
| Biopsy skin | 1 (<0.1) | 0 | 1 (<0.1) |
| Blood glucose decreased | 1 (<0.1) | 0 | 1 (<0.1) |
| Blood potassium decreased | 1 (<0.1) | 0 | 1 (<0.1) |
| Brain natriuretic peptide increased | 1 (<0.1) | 0 | 1 (<0.1) |
| C-reactive protein increased | 1 (<0.1) | 0 | 1 (<0.1) |
| Cardiac murmur | 1 (<0.1) | 0 | 1 (<0.1) |
| Colonoscopy | 1 (<0.1) | 0 | 1 (<0.1) |
| Lipase increased | 1 (<0.1) | 0 | 1 (<0.1) |
| Vitamin B12 decreased | 1 (<0.1) | 0 | 1 (<0.1) |
| Vitamin D decreased | 2 (<0.1) | 0 | 2 (<0.1) |
| Weight increased | 1 (<0.1) | 0 | 1 (<0.1) |
| Injury, poisoning and procedural complications | 180 (1.6) | 153 (1.3) | 333 (1.5) |
| Muscle strain | 18 (0.2) | 25 (0.2) | 43 (0.2) |
| Ligament sprain | 19 (0.2) | 15 (0.1) | 34 (0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Injury, poisoning and procedural complications (Cont.) | | | |
| Skin laceration | 20 (0.2) | 13 (0.1) | 33 (0.1) |
| Arthropod bite | 15 (0.1) | 10 (<0.1) | 25 (0.1) |
| Arthropod sting | 7 (<0.1) | 6 (<0.1) | 13 (<0.1) |
| Foot fracture | 6 (<0.1) | 6 (<0.1) | 12 (<0.1) |
| Limb injury | 2 (<0.1) | 6 (<0.1) | 8 (<0.1) |
| Contusion | 18 (0.2) | 5 (<0.1) | 23 (0.1) |
| Tooth fracture | 7 (<0.1) | 5 (<0.1) | 12 (<0.1) |
| Animal bite | 5 (<0.1) | 4 (<0.1) | 9 (<0.1) |
| Concussion | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Road traffic accident | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Skin abrasion | 12 (0.1) | 4 (<0.1) | 16 (<0.1) |
| Hand fracture | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Joint injury | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Meniscus injury | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Cartilage injury | 0 | 2 (<0.1) | 2 (<0.1) |
| Epicondylitis | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Fall | 6 (<0.1) | 2 (<0.1) | 8 (<0.1) |
| Ligament rupture | 0 | 2 (<0.1) | 2 (<0.1) |
| Procedural pain | 8 (<0.1) | 2 (<0.1) | 10 (<0.1) |
| Tendon injury | 0 | 2 (<0.1) | 2 (<0.1) |
| Upper limb fracture | 0 | 2 (<0.1) | 2 (<0.1) |
| Alcohol poisoning | 0 | 1 (<0.1) | 1 (<0.1) |
| Ankle fracture | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class | Placebo (N=11415) | mRNA-1273 (N=11414) | Total (N=22830) |
|---|----------------------|------------------------|--------------------|
| Preferred Term | n (%) | n (%) | n (%) |
| Injury, poisoning and procedural complications (Cont.) | | | |
| Back injury | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Bone fragmentation | 0 | 1 (<0.1) | 1 (<0.1) |
| Burns second degree | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Clavicle fracture | 0 | 1 (<0.1) | 1 (<0.1) |
| Corneal abrasion | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Exposure to SARS-CoV-2 | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Face injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Head injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Hypobarism | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection related reaction | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Joint dislocation | 0 | 1 (<0.1) | 1 (<0.1) |
| Ligament injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Lumbar vertebral fracture | 0 | 1 (<0.1) | 1 (<0.1) |
| Meniscus cyst | 0 | 1 (<0.1) | 1 (<0.1) |
| Muscle rupture | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Nasal injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Patella fracture | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Periorbital haematoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Periorbital haemorrhage | 0 | 1 (<0.1) | 1 (<0.1) |
| Post procedural haemorrhage | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Post-traumatic neck syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Post-traumatic pain | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Injury, poisoning and procedural complications (Cont.) | | | |
| Procedural headache | 0 | 1 (<0.1) | 1 (<0.1) |
| Respiratory fume inhalation disorder | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Rib fracture | 0 | 1 (<0.1) | 1 (<0.1) |
| Scar | 0 | 1 (<0.1) | 1 (<0.1) |
| Tendon rupture | 0 | 1 (<0.1) | 1 (<0.1) |
| Thermal burn | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Tibia fracture | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Tooth injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaccination complication | 0 | 1 (<0.1) | 1 (<0.1) |
| Wound | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Burns first degree | 1 (<0.1) | 0 | 1 (<0.1) |
| Exposure to toxic agent | 1 (<0.1) | 0 | 1 (<0.1) |
| Eyelid contusion | 1 (<0.1) | 0 | 1 (<0.1) |
| Fibula fracture | 1 (<0.1) | 0 | 1 (<0.1) |
| Foreign body | 1 (<0.1) | 0 | 1 (<0.1) |
| Hip fracture | 1 (<0.1) | 0 | 1 (<0.1) |
| Iliotibial band syndrome | 1 (<0.1) | 0 | 1 (<0.1) |
| Immunisation anxiety related reaction | 1 (<0.1) | 0 | 1 (<0.1) |
| Mouth injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Muscle injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Procedural anxiety | 1 (<0.1) | 0 | 1 (<0.1) |
| Procedural haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Procedural nausea | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Injury, poisoning and procedural complications (Cont.) | | | |
| Scratch | 1 (<0.1) | 0 | 1 (<0.1) |
| Sports injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Stress fracture | 3 (<0.1) | 0 | 3 (<0.1) |
| Sunburn | 1 (<0.1) | 0 | 1 (<0.1) |
| Superficial injury of eye | 1 (<0.1) | 0 | 1 (<0.1) |
| Ulna fracture | 1 (<0.1) | 0 | 1 (<0.1) |
| Venomous sting | 1 (<0.1) | 0 | 1 (<0.1) |
| Surgical and medical procedures | 5 (<0.1) | 7 (<0.1) | 12 (<0.1) |
| Axillary lymphadenectomy | 0 | 2 (<0.1) | 2 (<0.1) |
| Cholecystectomy | 0 | 1 (<0.1) | 1 (<0.1) |
| Dental operation | 0 | 1 (<0.1) | 1 (<0.1) |
| Endodontic procedure | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Skin neoplasm excision | 0 | 1 (<0.1) | 1 (<0.1) |
| Thyroidectomy | 0 | 1 (<0.1) | 1 (<0.1) |
| Cataract operation | 1 (<0.1) | 0 | 1 (<0.1) |
| Fracture treatment | 1 (<0.1) | 0 | 1 (<0.1) |
| Tooth repair | 2 (<0.1) | 0 | 2 (<0.1) |
| Social circumstances | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Menopause | 0 | 1 (<0.1) | 1 (<0.1) |
| Sexual abuse | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Product issues | 0 | 3 (<0.1) | 3 (<0.1) |
| Device breakage | 0 | 1 (<0.1) | 1 (<0.1) |
| Device dislocation | 0 | 1 (<0.1) | 1 (<0.1) |
| Embedded device | 0 | 1 (<0.1) | 1 (<0.1) |
| Uncoded | 112 (1.0) | 186 (1.6) | 298 (1.3) |
| Uncoded | 112 (1.0) | 186 (1.6) | 298 (1.3) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|---|------------------------------|--------------------------------|----------------------------|
| Number of Subjects Reporting Unsolicited Adverse Events | 734 (19.6) | 872 (23.1) | 1606 (21.4) |
| Number of Unsolicited Adverse Events | 1297 | 1603 | 2900 |
| Infections and infestations | 140 (3.7) | 115 (3.1) | 255 (3.4) |
| Urinary tract infection | 31 (0.8) | 17 (0.5) | 48 (0.6) |
| Sinusitis | 4 (0.1) | 9 (0.2) | 13 (0.2) |
| Herpes zoster | 3 (<0.1) | 6 (0.2) | 9 (0.1) |
| Gastroenteritis | 3 (<0.1) | 5 (0.1) | 8 (0.1) |
| Gingivitis | 1 (<0.1) | 5 (0.1) | 6 (<0.1) |
| COVID-19 | 11 (0.3) | 4 (0.1) | 15 (0.2) |
| Cellulitis | 5 (0.1) | 4 (0.1) | 9 (0.1) |
| Rhinovirus infection | 0 | 4 (0.1) | 4 (<0.1) |
| Tooth infection | 2 (<0.1) | 4 (0.1) | 6 (<0.1) |
| Upper respiratory tract infection | 5 (0.1) | 4 (0.1) | 9 (0.1) |
| Conjunctivitis | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Enterovirus infection | 0 | 3 (<0.1) | 3 (<0.1) |
| Herpes simplex | 0 | 3 (<0.1) | 3 (<0.1) |
| Hordeolum | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Laryngitis | 0 | 3 (<0.1) | 3 (<0.1) |
| Localised infection | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Staphylococcal infection | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Tooth abscess | 10 (0.3) | 3 (<0.1) | 13 (0.2) |
| Viral infection | 4 (0.1) | 3 (<0.1) | 7 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--------------------------------------|------------------------------|--------------------------------|----------------------------|
| Infections and infestations (Cont.) | | | |
| Cystitis | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Diverticulitis | 4 (0.1) | 2 (<0.1) | 6 (<0.1) |
| Fungal infection | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Oral herpes | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Paronychia | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Pharyngitis | 0 | 2 (<0.1) | 2 (<0.1) |
| Pneumonia | 6 (0.2) | 2 (<0.1) | 8 (0.1) |
| Subcutaneous abscess | 0 | 2 (<0.1) | 2 (<0.1) |
| Acute sinusitis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Appendicitis | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Chronic sinusitis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Dermatophytosis of nail | 0 | 1 (<0.1) | 1 (<0.1) |
| Ear infection | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Folliculitis | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Impetigo | 0 | 1 (<0.1) | 1 (<0.1) |
| Infected dermal cyst | 0 | 1 (<0.1) | 1 (<0.1) |
| Joint abscess | 0 | 1 (<0.1) | 1 (<0.1) |
| Latent tuberculosis | 0 | 1 (<0.1) | 1 (<0.1) |
| Onychomycosis | 0 | 1 (<0.1) | 1 (<0.1) |
| Otitis media acute | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Pneumonia staphylococcal | 0 | 1 (<0.1) | 1 (<0.1) |
| Rhinitis | 4 (0.1) | 1 (<0.1) | 5 (<0.1) |
| Sepsis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Sialoadenitis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|---|------------------------------|--------------------------------|----------------------------|
| Infections and infestations (Cont.) | | | |
| Tinea pedis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Vaginal infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Viral upper respiratory tract infection | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Vulvovaginal candidiasis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Blastocystis infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Candida infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Denture stomatitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Fungal skin infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Gardnerella infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Genital herpes simplex | 1 (<0.1) | 0 | 1 (<0.1) |
| Kidney infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Labyrinthitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Nasopharyngitis | 2 (<0.1) | 0 | 2 (<0.1) |
| Oral candidiasis | 1 (<0.1) | 0 | 1 (<0.1) |
| Osteomyelitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Otitis externa | 3 (<0.1) | 0 | 3 (<0.1) |
| Pharyngitis streptococcal | 2 (<0.1) | 0 | 2 (<0.1) |
| Respiratory tract infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Skin infection | 2 (<0.1) | 0 | 2 (<0.1) |
| Soft tissue infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Streptococcal sepsis | 1 (<0.1) | 0 | 1 (<0.1) |
| Tinea cruris | 1 (<0.1) | 0 | 1 (<0.1) |
| Viral rhinitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Vulvovaginal mycotic infection | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--|------------------------------|--------------------------------|----------------------------|
| Infections and infestations (Cont.) | | | |
| Wound infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 22 (0.6) | 19 (0.5) | 41 (0.5) |
| Basal cell carcinoma | 7 (0.2) | 4 (0.1) | 11 (0.1) |
| Prostate cancer | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Benign hepatic neoplasm | 0 | 1 (<0.1) | 1 (<0.1) |
| Benign neoplasm of thyroid gland | 0 | 1 (<0.1) | 1 (<0.1) |
| Chronic lymphocytic leukaemia | 0 | 1 (<0.1) | 1 (<0.1) |
| Chronic myelomonocytic leukaemia | 0 | 1 (<0.1) | 1 (<0.1) |
| Keratoacanthoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Lip squamous cell carcinoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Lipoma | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Malignant melanoma | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Meningioma benign | 0 | 1 (<0.1) | 1 (<0.1) |
| Nasopharyngeal neoplasm benign | 0 | 1 (<0.1) | 1 (<0.1) |
| Neoplasm malignant | 0 | 1 (<0.1) | 1 (<0.1) |
| Rectal cancer | 0 | 1 (<0.1) | 1 (<0.1) |
| Squamous cell carcinoma | 6 (0.2) | 1 (<0.1) | 7 (<0.1) |
| Bladder neoplasm | 1 (<0.1) | 0 | 1 (<0.1) |
| Breast cancer stage I | 1 (<0.1) | 0 | 1 (<0.1) |
| Intraductal proliferative breast lesion | 1 (<0.1) | 0 | 1 (<0.1) |
| Skin cancer | 1 (<0.1) | 0 | 1 (<0.1) |
| Squamous cell carcinoma of skin | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--------------------------------------|------------------------------|--------------------------------|----------------------------|
| Blood and lymphatic system disorders | 9 (0.2) | 19 (0.5) | 28 (0.4) |
| Lymphadenopathy | 7 (0.2) | 16 (0.4) | 23 (0.3) |
| Anaemia | 0 | 1 (<0.1) | 1 (<0.1) |
| Blood loss anaemia | 0 | 1 (<0.1) | 1 (<0.1) |
| Leukocytosis | 0 | 1 (<0.1) | 1 (<0.1) |
| Lymph node pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Lymphadenitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Immune system disorders | 6 (0.2) | 6 (0.2) | 12 (0.2) |
| Hypersensitivity | 0 | 3 (<0.1) | 3 (<0.1) |
| Seasonal allergy | 4 (0.1) | 2 (<0.1) | 6 (<0.1) |
| Type IV hypersensitivity reaction | 0 | 1 (<0.1) | 1 (<0.1) |
| Allergy to chemicals | 1 (<0.1) | 0 | 1 (<0.1) |
| Drug hypersensitivity | 1 (<0.1) | 0 | 1 (<0.1) |
| Endocrine disorders | 5 (0.1) | 0 | 5 (<0.1) |
| Addison's disease | 1 (<0.1) | 0 | 1 (<0.1) |
| Androgen deficiency | 1 (<0.1) | 0 | 1 (<0.1) |
| Hypothyroidism | 3 (<0.1) | 0 | 3 (<0.1) |
| Metabolism and nutrition disorders | 15 (0.4) | 27 (0.7) | 42 (0.6) |
| Hyperlipidaemia | 2 (<0.1) | 7 (0.2) | 9 (0.1) |
| Dehydration | 1 (<0.1) | 4 (0.1) | 5 (<0.1) |
| Hypercholesterolaemia | 1 (<0.1) | 4 (0.1) | 5 (<0.1) |
| Type 2 diabetes mellitus | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--|------------------------------|--------------------------------|----------------------------|
| Metabolism and nutrition disorders (Cont.) | | | |
| Hyponatraemia | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Vitamin D deficiency | 0 | 2 (<0.1) | 2 (<0.1) |
| Decreased appetite | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Diabetes mellitus | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Diabetes mellitus inadequate control | 0 | 1 (<0.1) | 1 (<0.1) |
| Gout | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Hyperglycaemia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Insulin resistance | 0 | 1 (<0.1) | 1 (<0.1) |
| Iron deficiency | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Vitamin B12 deficiency | 0 | 1 (<0.1) | 1 (<0.1) |
| Hypocalcaemia | 1 (<0.1) | 0 | 1 (<0.1) |
| Hypoglycaemia | 2 (<0.1) | 0 | 2 (<0.1) |
| Psychiatric disorders | 9 (0.2) | 20 (0.5) | 29 (0.4) |
| Anxiety | 2 (<0.1) | 6 (0.2) | 8 (0.1) |
| Depression | 0 | 3 (<0.1) | 3 (<0.1) |
| Insomnia | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Nightmare | 0 | 3 (<0.1) | 3 (<0.1) |
| Sleep disorder | 0 | 2 (<0.1) | 2 (<0.1) |
| Bruxism | 0 | 1 (<0.1) | 1 (<0.1) |
| Drug use disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Hallucination | 0 | 1 (<0.1) | 1 (<0.1) |
| Adjustment disorder with depressed mood | 1 (<0.1) | 0 | 1 (<0.1) |
| Confusional state | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--------------------------------------|------------------------------|--------------------------------|----------------------------|
| Psychiatric disorders (Cont.) | | | |
| Generalised anxiety disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Mental status changes | 1 (<0.1) | 0 | 1 (<0.1) |
| Nervous system disorders | 113 (3.0) | 135 (3.6) | 248 (3.3) |
| Headache | 74 (2.0) | 89 (2.4) | 163 (2.2) |
| Dizziness | 14 (0.4) | 16 (0.4) | 30 (0.4) |
| Sinus headache | 1 (<0.1) | 6 (0.2) | 7 (<0.1) |
| Paraesthesia | 2 (<0.1) | 4 (0.1) | 6 (<0.1) |
| Sciatica | 2 (<0.1) | 4 (0.1) | 6 (<0.1) |
| Cervical radiculopathy | 0 | 3 (<0.1) | 3 (<0.1) |
| Ageusia | 0 | 2 (<0.1) | 2 (<0.1) |
| Dysgeusia | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Hyperaesthesia | 0 | 2 (<0.1) | 2 (<0.1) |
| Hypoaesthesia | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Syncope | 4 (0.1) | 2 (<0.1) | 6 (<0.1) |
| Amnesia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Balance disorder | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Carpal tunnel syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Cerebrovascular accident | 0 | 1 (<0.1) | 1 (<0.1) |
| Disturbance in attention | 0 | 1 (<0.1) | 1 (<0.1) |
| Embolic stroke | 0 | 1 (<0.1) | 1 (<0.1) |
| Essential tremor | 0 | 1 (<0.1) | 1 (<0.1) |
| Hyposmia | 0 | 1 (<0.1) | 1 (<0.1) |
| Migraine | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--------------------------------------|------------------------------|--------------------------------|----------------------------|
| Nervous system disorders (Cont.) | | | |
| Neuralgia | 0 | 1 (<0.1) | 1 (<0.1) |
| Poor quality sleep | 0 | 1 (<0.1) | 1 (<0.1) |
| Tension headache | 0 | 1 (<0.1) | 1 (<0.1) |
| Toxic encephalopathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Transient ischaemic attack | 0 | 1 (<0.1) | 1 (<0.1) |
| Dysaesthesia | 1 (<0.1) | 0 | 1 (<0.1) |
| Ischaemic stroke | 1 (<0.1) | 0 | 1 (<0.1) |
| Lumbar radiculopathy | 1 (<0.1) | 0 | 1 (<0.1) |
| Nerve compression | 1 (<0.1) | 0 | 1 (<0.1) |
| Post-traumatic headache | 1 (<0.1) | 0 | 1 (<0.1) |
| Presyncope | 2 (<0.1) | 0 | 2 (<0.1) |
| Restless legs syndrome | 1 (<0.1) | 0 | 1 (<0.1) |
| Speech disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Taste disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Tremor | 1 (<0.1) | 0 | 1 (<0.1) |
| Eye disorders | 20 (0.5) | 16 (0.4) | 36 (0.5) |
| Eye irritation | 0 | 2 (<0.1) | 2 (<0.1) |
| Eye pain | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Eye pruritus | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Accommodation disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Dry eye | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Eye inflammation | 0 | 1 (<0.1) | 1 (<0.1) |
| Eye swelling | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--------------------------------------|------------------------------|--------------------------------|----------------------------|
| Eye disorders (Cont.) | | | |
| Glaucoma | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Retinal detachment | 0 | 1 (<0.1) | 1 (<0.1) |
| Swelling of eyelid | 0 | 1 (<0.1) | 1 (<0.1) |
| Visual impairment | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Vitreous disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Vitreous floaters | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Blepharitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Conjunctival haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Conjunctival irritation | 1 (<0.1) | 0 | 1 (<0.1) |
| Conjunctivitis allergic | 1 (<0.1) | 0 | 1 (<0.1) |
| Conjunctivochalasis | 1 (<0.1) | 0 | 1 (<0.1) |
| Dacryostenosis acquired | 1 (<0.1) | 0 | 1 (<0.1) |
| Eye discharge | 1 (<0.1) | 0 | 1 (<0.1) |
| Macular hole | 1 (<0.1) | 0 | 1 (<0.1) |
| Ocular hyperaemia | 1 (<0.1) | 0 | 1 (<0.1) |
| Periorbital oedema | 1 (<0.1) | 0 | 1 (<0.1) |
| Periorbital swelling | 1 (<0.1) | 0 | 1 (<0.1) |
| Strabismus | 1 (<0.1) | 0 | 1 (<0.1) |
| Ulcerative keratitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Vision blurred | 1 (<0.1) | 0 | 1 (<0.1) |
| Ear and labyrinth disorders | 15 (0.4) | 17 (0.5) | 32 (0.4) |
| Vertigo | 6 (0.2) | 6 (0.2) | 12 (0.2) |
| Vertigo positional | 0 | 3 (<0.1) | 3 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--------------------------------------|------------------------------|--------------------------------|----------------------------|
| Ear and labyrinth disorders (Cont.) | | | |
| Tinnitus | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Cerumen impaction | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Deafness unilateral | 0 | 1 (<0.1) | 1 (<0.1) |
| Ear congestion | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Ear pain | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Middle ear effusion | 0 | 1 (<0.1) | 1 (<0.1) |
| Motion sickness | 0 | 1 (<0.1) | 1 (<0.1) |
| Ear discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Excessive cerumen production | 1 (<0.1) | 0 | 1 (<0.1) |
| Otorrhoea | 1 (<0.1) | 0 | 1 (<0.1) |
| Tympanic membrane perforation | 2 (<0.1) | 0 | 2 (<0.1) |
| Cardiac disorders | 20 (0.5) | 25 (0.7) | 45 (0.6) |
| Atrial fibrillation | 4 (0.1) | 8 (0.2) | 12 (0.2) |
| Angina pectoris | 0 | 3 (<0.1) | 3 (<0.1) |
| Coronary artery disease | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Palpitations | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Arrhythmia | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Cardiac failure congestive | 0 | 2 (<0.1) | 2 (<0.1) |
| Tachycardia | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Acute coronary syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Acute myocardial infarction | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Bradycardia | 6 (0.2) | 1 (<0.1) | 7 (<0.1) |
| Cardio-respiratory arrest | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--------------------------------------|------------------------------|--------------------------------|----------------------------|
| Cardiac disorders (Cont.) | | | |
| Cardiomyopathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Sinus tachycardia | 0 | 1 (<0.1) | 1 (<0.1) |
| Atrial flutter | 1 (<0.1) | 0 | 1 (<0.1) |
| Cardiac failure | 1 (<0.1) | 0 | 1 (<0.1) |
| Cardiac failure acute | 1 (<0.1) | 0 | 1 (<0.1) |
| Ventricular fibrillation | 1 (<0.1) | 0 | 1 (<0.1) |
| Vascular disorders | 51 (1.4) | 52 (1.4) | 103 (1.4) |
| Hypertension | 36 (1.0) | 34 (0.9) | 70 (0.9) |
| Hot flush | 3 (<0.1) | 7 (0.2) | 10 (0.1) |
| Flushing | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Hypertensive urgency | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Hypotension | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Aortic aneurysm | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Essential hypertension | 0 | 1 (<0.1) | 1 (<0.1) |
| Haematoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Orthostatic hypotension | 0 | 1 (<0.1) | 1 (<0.1) |
| Peripheral artery occlusion | 0 | 1 (<0.1) | 1 (<0.1) |
| Systolic hypertension | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Fibromuscular dysplasia | 1 (<0.1) | 0 | 1 (<0.1) |
| Peripheral vascular disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Phlebitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Vasodilatation | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|---|------------------------------|--------------------------------|----------------------------|
| Respiratory, thoracic and mediastinal disorders | 106 (2.8) | 102 (2.7) | 208 (2.8) |
| Rhinorrhoea | 27 (0.7) | 34 (0.9) | 61 (0.8) |
| Oropharyngeal pain | 26 (0.7) | 25 (0.7) | 51 (0.7) |
| Cough | 16 (0.4) | 24 (0.6) | 40 (0.5) |
| Nasal congestion | 23 (0.6) | 24 (0.6) | 47 (0.6) |
| Dyspnoea | 6 (0.2) | 9 (0.2) | 15 (0.2) |
| Asthma | 1 (<0.1) | 5 (0.1) | 6 (<0.1) |
| Upper-airway cough syndrome | 1 (<0.1) | 5 (0.1) | 6 (<0.1) |
| Sneezing | 1 (<0.1) | 4 (0.1) | 5 (<0.1) |
| Tachypnoea | 4 (0.1) | 4 (0.1) | 8 (0.1) |
| Dysphonia | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Epistaxis | 5 (0.1) | 3 (<0.1) | 8 (0.1) |
| Chronic obstructive pulmonary disease | 4 (0.1) | 2 (<0.1) | 6 (<0.1) |
| Respiratory tract congestion | 0 | 2 (<0.1) | 2 (<0.1) |
| Sinus congestion | 5 (0.1) | 2 (<0.1) | 7 (<0.1) |
| Throat irritation | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Bronchiectasis | 0 | 1 (<0.1) | 1 (<0.1) |
| Bronchospasm | 0 | 1 (<0.1) | 1 (<0.1) |
| Dry throat | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Dyspnoea exertional | 0 | 1 (<0.1) | 1 (<0.1) |
| Paranasal sinus discomfort | 0 | 1 (<0.1) | 1 (<0.1) |
| Productive cough | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Respiratory disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Rhinitis allergic | 4 (0.1) | 1 (<0.1) | 5 (<0.1) |
| Sinus pain | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--|------------------------------|--------------------------------|----------------------------|
| Respiratory, thoracic and mediastinal disorders (Cont.) | | | |
| Sleep apnoea syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Wheezing | 0 | 1 (<0.1) | 1 (<0.1) |
| Nasal septum deviation | 1 (<0.1) | 0 | 1 (<0.1) |
| Oropharyngeal discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Pharyngeal erythema | 2 (<0.1) | 0 | 2 (<0.1) |
| Pleural effusion | 2 (<0.1) | 0 | 2 (<0.1) |
| Pulmonary congestion | 1 (<0.1) | 0 | 1 (<0.1) |
| Tonsillar exudate | 1 (<0.1) | 0 | 1 (<0.1) |
| Tonsillar hypertrophy | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastrointestinal disorders | 99 (2.6) | 112 (3.0) | 211 (2.8) |
| Diarrhoea | 43 (1.1) | 40 (1.1) | 83 (1.1) |
| Nausea | 19 (0.5) | 29 (0.8) | 48 (0.6) |
| Gastrooesophageal reflux disease | 2 (<0.1) | 12 (0.3) | 14 (0.2) |
| Vomiting | 7 (0.2) | 11 (0.3) | 18 (0.2) |
| Toothache | 4 (0.1) | 7 (0.2) | 11 (0.1) |
| Dyspepsia | 1 (<0.1) | 5 (0.1) | 6 (<0.1) |
| Abdominal pain upper | 3 (<0.1) | 4 (0.1) | 7 (<0.1) |
| Abdominal pain | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Dental caries | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Abdominal pain lower | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Constipation | 4 (0.1) | 2 (<0.1) | 6 (<0.1) |
| Inguinal hernia | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--------------------------------------|------------------------------|--------------------------------|----------------------------|
| Gastrointestinal disorders (Cont.) | | | |
| Abdominal discomfort | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Colitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Dry mouth | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Food poisoning | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Hiatus hernia | 0 | 1 (<0.1) | 1 (<0.1) |
| Hyperaesthesia teeth | 0 | 1 (<0.1) | 1 (<0.1) |
| Hypoaesthesia oral | 0 | 1 (<0.1) | 1 (<0.1) |
| Lip swelling | 0 | 1 (<0.1) | 1 (<0.1) |
| Oesophageal pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Pancreatitis acute | 0 | 1 (<0.1) | 1 (<0.1) |
| Paraesthesia oral | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Rectal haemorrhage | 0 | 1 (<0.1) | 1 (<0.1) |
| Salivary gland calculus | 0 | 1 (<0.1) | 1 (<0.1) |
| Salivary hypersecretion | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Stomatitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Swollen tongue | 0 | 1 (<0.1) | 1 (<0.1) |
| Tooth discolouration | 0 | 1 (<0.1) | 1 (<0.1) |
| Volvulus | 0 | 1 (<0.1) | 1 (<0.1) |
| Aphthous ulcer | 1 (<0.1) | 0 | 1 (<0.1) |
| Duodenal ulcer haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastritis | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastrointestinal motility disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Gingival pain | 2 (<0.1) | 0 | 2 (<0.1) |
| Intestinal obstruction | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--|------------------------------|--------------------------------|----------------------------|
| Gastrointestinal disorders (Cont.) | | | |
| Large intestine polyp | 2 (<0.1) | 0 | 2 (<0.1) |
| Oral discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Oral pain | 2 (<0.1) | 0 | 2 (<0.1) |
| Retching | 1 (<0.1) | 0 | 1 (<0.1) |
| Umbilical hernia | 1 (<0.1) | 0 | 1 (<0.1) |
| Hepatobiliary disorders | 0 | 3 (<0.1) | 3 (<0.1) |
| Bile duct stone | 0 | 1 (<0.1) | 1 (<0.1) |
| Cholecystitis acute | 0 | 1 (<0.1) | 1 (<0.1) |
| Cholelithiasis | 0 | 1 (<0.1) | 1 (<0.1) |
| Skin and subcutaneous tissue disorders | 49 (1.3) | 63 (1.7) | 112 (1.5) |
| Rash | 4 (0.1) | 10 (0.3) | 14 (0.2) |
| Pruritus | 7 (0.2) | 8 (0.2) | 15 (0.2) |
| Erythema | 3 (<0.1) | 7 (0.2) | 10 (0.1) |
| Urticaria | 3 (<0.1) | 6 (0.2) | 9 (0.1) |
| Actinic keratosis | 0 | 3 (<0.1) | 3 (<0.1) |
| Dermatitis atopic | 0 | 3 (<0.1) | 3 (<0.1) |
| Dermatitis contact | 10 (0.3) | 3 (<0.1) | 13 (0.2) |
| Hyperhidrosis | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Dermatitis | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Neurodermatitis | 0 | 2 (<0.1) | 2 (<0.1) |
| Night sweats | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Rash pruritic | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--|------------------------------|--------------------------------|----------------------------|
| Skin and subcutaneous tissue disorders (Cont.) | | | |
| Rosacea | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Ecchymosis | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Eczema | 0 | 1 (<0.1) | 1 (<0.1) |
| Ingrowing nail | 0 | 1 (<0.1) | 1 (<0.1) |
| Macule | 0 | 1 (<0.1) | 1 (<0.1) |
| Nail disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Pityriasis rosea | 0 | 1 (<0.1) | 1 (<0.1) |
| Rash erythematous | 0 | 1 (<0.1) | 1 (<0.1) |
| Rash papular | 0 | 1 (<0.1) | 1 (<0.1) |
| Skin lesion | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Skin mass | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Solar lentigo | 0 | 1 (<0.1) | 1 (<0.1) |
| Angioedema | 1 (<0.1) | 0 | 1 (<0.1) |
| Cold sweat | 1 (<0.1) | 0 | 1 (<0.1) |
| Dermal cyst | 1 (<0.1) | 0 | 1 (<0.1) |
| Dermatitis bullous | 1 (<0.1) | 0 | 1 (<0.1) |
| Lichenoid keratosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Psoriasis | 1 (<0.1) | 0 | 1 (<0.1) |
| Scab | 1 (<0.1) | 0 | 1 (<0.1) |
| Seborrheic dermatitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Telangiectasia | 1 (<0.1) | 0 | 1 (<0.1) |
| Urticaria papular | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class | Placebo (N=3750) | mRNA-1273 (N=3770) | Total (N=7520) |
|---|---------------------|-----------------------|-------------------|
| Preferred Term | n (%) | n (%) | n (%) |
| Musculoskeletal and connective tissue disorders | 143 (3.8) | 164 (4.4) | 307 (4.1) |
| Arthralgia | 41 (1.1) | 51 (1.4) | 92 (1.2) |
| Myalgia | 30 (0.8) | 41 (1.1) | 71 (0.9) |
| Back pain | 25 (0.7) | 21 (0.6) | 46 (0.6) |
| Pain in extremity | 17 (0.5) | 14 (0.4) | 31 (0.4) |
| Musculoskeletal pain | 5 (0.1) | 9 (0.2) | 14 (0.2) |
| Neck pain | 7 (0.2) | 9 (0.2) | 16 (0.2) |
| Muscle spasms | 5 (0.1) | 8 (0.2) | 13 (0.2) |
| Musculoskeletal stiffness | 1 (<0.1) | 6 (0.2) | 7 (<0.1) |
| Tendonitis | 4 (0.1) | 4 (0.1) | 8 (0.1) |
| Arthritis | 0 | 3 (<0.1) | 3 (<0.1) |
| Joint swelling | 0 | 3 (<0.1) | 3 (<0.1) |
| Osteoporosis | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Muscular weakness | 0 | 2 (<0.1) | 2 (<0.1) |
| Rotator cuff syndrome | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Spinal stenosis | 0 | 2 (<0.1) | 2 (<0.1) |
| Trigger finger | 0 | 2 (<0.1) | 2 (<0.1) |
| Bursitis | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Costochondritis | 0 | 1 (<0.1) | 1 (<0.1) |
| Flank pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Joint range of motion decreased | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Joint stiffness | 0 | 1 (<0.1) | 1 (<0.1) |
| Limb discomfort | 0 | 1 (<0.1) | 1 (<0.1) |
| Muscle fatigue | 0 | 1 (<0.1) | 1 (<0.1) |
| Muscle tightness | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--|------------------------------|--------------------------------|----------------------------|
| Musculoskeletal and connective tissue disorders (Cont.) | | | |
| Musculoskeletal chest pain | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Neck mass | 0 | 1 (<0.1) | 1 (<0.1) |
| Osteoarthritis | 7 (0.2) | 1 (<0.1) | 8 (0.1) |
| Periarthritis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Spinal osteoarthritis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Spondylitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Tendon disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Fibromyalgia | 1 (<0.1) | 0 | 1 (<0.1) |
| Foot deformity | 1 (<0.1) | 0 | 1 (<0.1) |
| Groin pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Pain in jaw | 2 (<0.1) | 0 | 2 (<0.1) |
| Polymyalgia rheumatica | 1 (<0.1) | 0 | 1 (<0.1) |
| Renal and urinary disorders | 18 (0.5) | 16 (0.4) | 34 (0.5) |
| Nephrolithiasis | 7 (0.2) | 6 (0.2) | 13 (0.2) |
| Haematuria | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Chronic kidney disease | 0 | 1 (<0.1) | 1 (<0.1) |
| Cystitis interstitial | 0 | 1 (<0.1) | 1 (<0.1) |
| Dysuria | 0 | 1 (<0.1) | 1 (<0.1) |
| Lower urinary tract symptoms | 0 | 1 (<0.1) | 1 (<0.1) |
| Pollakiuria | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Polyuria | 0 | 1 (<0.1) | 1 (<0.1) |
| Urinary hesitation | 0 | 1 (<0.1) | 1 (<0.1) |

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Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--|------------------------------|--------------------------------|----------------------------|
| Renal and urinary disorders (Cont.) | | | |
| Urinary retention | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Acute kidney injury | 2 (<0.1) | 0 | 2 (<0.1) |
| Chromaturia | 1 (<0.1) | 0 | 1 (<0.1) |
| Micturition urgency | 1 (<0.1) | 0 | 1 (<0.1) |
| Renal colic | 1 (<0.1) | 0 | 1 (<0.1) |
| Renal mass | 1 (<0.1) | 0 | 1 (<0.1) |
| Urge incontinence | 1 (<0.1) | 0 | 1 (<0.1) |
| Urinary incontinence | 1 (<0.1) | 0 | 1 (<0.1) |
| Reproductive system and breast disorders | 3 (<0.1) | 13 (0.3) | 16 (0.2) |
| Benign prostatic hyperplasia | 1 (<0.1) | 5 (0.1) | 6 (<0.1) |
| Erectile dysfunction | 0 | 2 (<0.1) | 2 (<0.1) |
| Adenomyosis | 0 | 1 (<0.1) | 1 (<0.1) |
| Balanoposthitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Breast discharge | 0 | 1 (<0.1) | 1 (<0.1) |
| Breast mass | 0 | 1 (<0.1) | 1 (<0.1) |
| Breast swelling | 0 | 1 (<0.1) | 1 (<0.1) |
| Ovarian cyst | 0 | 1 (<0.1) | 1 (<0.1) |
| Prostatitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Prostatomegaly | 1 (<0.1) | 0 | 1 (<0.1) |
| General disorders and administration site conditions | 128 (3.4) | 214 (5.7) | 342 (4.5) |
| Fatigue | 58 (1.5) | 92 (2.4) | 150 (2.0) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--|------------------------------|--------------------------------|----------------------------|
| General disorders and administration site conditions (Cont.) | | | |
| Injection site erythema | 7 (0.2) | 32 (0.8) | 39 (0.5) |
| Injection site pain | 13 (0.3) | 28 (0.7) | 41 (0.5) |
| Injection site pruritus | 2 (<0.1) | 18 (0.5) | 20 (0.3) |
| Chills | 13 (0.3) | 16 (0.4) | 29 (0.4) |
| Pyrexia | 4 (0.1) | 13 (0.3) | 17 (0.2) |
| Injection site swelling | 5 (0.1) | 12 (0.3) | 17 (0.2) |
| Pain | 10 (0.3) | 12 (0.3) | 22 (0.3) |
| Injection site rash | 0 | 8 (0.2) | 8 (0.1) |
| Injection site induration | 3 (<0.1) | 4 (0.1) | 7 (<0.1) |
| Axillary pain | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Injection site bruising | 6 (0.2) | 3 (<0.1) | 9 (0.1) |
| Oedema peripheral | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Injection site warmth | 0 | 2 (<0.1) | 2 (<0.1) |
| Peripheral swelling | 4 (0.1) | 2 (<0.1) | 6 (<0.1) |
| Vaccination site pain | 0 | 2 (<0.1) | 2 (<0.1) |
| Asthenia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Chest discomfort | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Chest pain | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Exercise tolerance decreased | 0 | 1 (<0.1) | 1 (<0.1) |
| Feeling abnormal | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Feeling hot | 0 | 1 (<0.1) | 1 (<0.1) |
| Inflammation | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site haemorrhage | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |

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Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--|------------------------------|--------------------------------|----------------------------|
| General disorders and administration site conditions (Cont.) | | | |
| Injection site joint pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site lymphadenopathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site paraesthesia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Injection site reaction | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site scab | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site urticaria | 0 | 1 (<0.1) | 1 (<0.1) |
| Malaise | 5 (0.1) | 1 (<0.1) | 6 (<0.1) |
| Reactogenicity event | 0 | 1 (<0.1) | 1 (<0.1) |
| Swelling | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Temperature intolerance | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaccination site lymphadenopathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Vessel puncture site haemorrhage | 0 | 1 (<0.1) | 1 (<0.1) |
| Facial pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Gait disturbance | 1 (<0.1) | 0 | 1 (<0.1) |
| Incarcerated hernia | 1 (<0.1) | 0 | 1 (<0.1) |
| Injection site discolouration | 1 (<0.1) | 0 | 1 (<0.1) |
| Injection site haematoma | 1 (<0.1) | 0 | 1 (<0.1) |
| Injection site hypoaesthesia | 1 (<0.1) | 0 | 1 (<0.1) |
| Injection site mass | 1 (<0.1) | 0 | 1 (<0.1) |
| Injection site nodule | 1 (<0.1) | 0 | 1 (<0.1) |
| Non-cardiac chest pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Pelvic mass | 1 (<0.1) | 0 | 1 (<0.1) |
| Thirst | 1 (<0.1) | 0 | 1 (<0.1) |

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Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--|------------------------------|--------------------------------|----------------------------|
| General disorders and administration site conditions (Cont.) | | | |
| Vaccination site inflammation | 1 (<0.1) | 0 | 1 (<0.1) |
| Vessel puncture site bruise | 1 (<0.1) | 0 | 1 (<0.1) |
| Investigations | 15 (0.4) | 30 (0.8) | 45 (0.6) |
| Blood pressure increased | 6 (0.2) | 10 (0.3) | 16 (0.2) |
| Blood pressure systolic increased | 4 (0.1) | 6 (0.2) | 10 (0.1) |
| Blood pressure diastolic increased | 0 | 2 (<0.1) | 2 (<0.1) |
| Blood creatine increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Blood creatinine increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Blood glucose decreased | 0 | 1 (<0.1) | 1 (<0.1) |
| Blood glucose increased | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Blood parathyroid hormone increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Blood pressure systolic decreased | 0 | 1 (<0.1) | 1 (<0.1) |
| Body temperature decreased | 0 | 1 (<0.1) | 1 (<0.1) |
| Cardiac murmur | 0 | 1 (<0.1) | 1 (<0.1) |
| Glycosylated haemoglobin increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Heart rate increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Neutrophil count increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Prostatic specific antigen increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Weight decreased | 0 | 1 (<0.1) | 1 (<0.1) |
| Blood cholesterol increased | 1 (<0.1) | 0 | 1 (<0.1) |
| Blood iron decreased | 2 (<0.1) | 0 | 2 (<0.1) |
| Mammogram abnormal | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--|------------------------------|--------------------------------|----------------------------|
| Injury, poisoning and procedural complications | 82 (2.2) | 85 (2.3) | 167 (2.2) |
| Arthropod bite | 6 (0.2) | 9 (0.2) | 15 (0.2) |
| Contusion | 8 (0.2) | 9 (0.2) | 17 (0.2) |
| Fall | 7 (0.2) | 9 (0.2) | 16 (0.2) |
| Skin laceration | 5 (0.1) | 7 (0.2) | 12 (0.2) |
| Ligament sprain | 4 (0.1) | 6 (0.2) | 10 (0.1) |
| Muscle strain | 6 (0.2) | 6 (0.2) | 12 (0.2) |
| Procedural pain | 3 (<0.1) | 6 (0.2) | 9 (0.1) |
| Tooth fracture | 5 (0.1) | 5 (0.1) | 10 (0.1) |
| Limb injury | 3 (<0.1) | 4 (0.1) | 7 (<0.1) |
| Foot fracture | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Cervical vertebral fracture | 0 | 2 (<0.1) | 2 (<0.1) |
| Facial bones fracture | 0 | 2 (<0.1) | 2 (<0.1) |
| Hand fracture | 0 | 2 (<0.1) | 2 (<0.1) |
| Heat exhaustion | 0 | 2 (<0.1) | 2 (<0.1) |
| Rib fracture | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Road traffic accident | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Skin abrasion | 5 (0.1) | 2 (<0.1) | 7 (<0.1) |
| Wrist fracture | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Animal bite | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Animal scratch | 0 | 1 (<0.1) | 1 (<0.1) |
| Arthropod sting | 6 (0.2) | 1 (<0.1) | 7 (<0.1) |
| Back injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Burns first degree | 0 | 1 (<0.1) | 1 (<0.1) |
| Concussion | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|---|------------------------------|--------------------------------|----------------------------|
| Injury, poisoning and procedural complications (Cont.) | | | |
| Craniocerebral injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Epicondylitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Femoral neck fracture | 0 | 1 (<0.1) | 1 (<0.1) |
| Fibula fracture | 0 | 1 (<0.1) | 1 (<0.1) |
| Head injury | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Hip fracture | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Lower limb fracture | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Meniscus injury | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Muscle rupture | 0 | 1 (<0.1) | 1 (<0.1) |
| Overdose | 0 | 1 (<0.1) | 1 (<0.1) |
| Scratch | 0 | 1 (<0.1) | 1 (<0.1) |
| Subdural haematoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Tendon rupture | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Thermal burn | 0 | 1 (<0.1) | 1 (<0.1) |
| Traumatic liver injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Abdominal injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Ankle fracture | 1 (<0.1) | 0 | 1 (<0.1) |
| Bone contusion | 2 (<0.1) | 0 | 2 (<0.1) |
| Exposure to SARS-CoV-2 | 1 (<0.1) | 0 | 1 (<0.1) |
| Eye injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Foreign body | 1 (<0.1) | 0 | 1 (<0.1) |
| Foreign body in ear | 1 (<0.1) | 0 | 1 (<0.1) |
| Humerus fracture | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|---|------------------------------|--------------------------------|----------------------------|
| Injury, poisoning and procedural complications (Cont.) | | | |
| Joint injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Ligament rupture | 1 (<0.1) | 0 | 1 (<0.1) |
| Lip injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Lumbar vertebral fracture | 1 (<0.1) | 0 | 1 (<0.1) |
| Nail injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Post procedural haematoma | 1 (<0.1) | 0 | 1 (<0.1) |
| Post-traumatic pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Tendon injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Ulnar nerve injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Wound | 1 (<0.1) | 0 | 1 (<0.1) |
| Surgical and medical procedures | 5 (0.1) | 8 (0.2) | 13 (0.2) |
| Ankle arthroplasty | 0 | 1 (<0.1) | 1 (<0.1) |
| Curettage of chalazion | 0 | 1 (<0.1) | 1 (<0.1) |
| Cyst removal | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Endodontic procedure | 0 | 1 (<0.1) | 1 (<0.1) |
| Lipoma excision | 0 | 1 (<0.1) | 1 (<0.1) |
| Phlebectomy | 0 | 1 (<0.1) | 1 (<0.1) |
| Skin operation | 0 | 1 (<0.1) | 1 (<0.1) |
| Transurethral prostatectomy | 0 | 1 (<0.1) | 1 (<0.1) |
| Carpal tunnel decompression | 1 (<0.1) | 0 | 1 (<0.1) |
| Hip arthroplasty | 1 (<0.1) | 0 | 1 (<0.1) |
| Tooth extraction | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.8.4

Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|---|------------------------------|--------------------------------|----------------------------|
| Surgical and medical procedures (Cont.) | | | |
| Umbilical hernia repair | 1 (<0.1) | 0 | 1 (<0.1) |
| Product issues | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Device breakage | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Lead dislodgement | 1 (<0.1) | 0 | 1 (<0.1) |
| Uncoded | 41 (1.1) | 58 (1.5) | 99 (1.3) |
| Uncoded | 41 (1.1) | 58 (1.5) | 99 (1.3) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.11.1

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Number of Subjects Reporting Unsolicited Adverse Events | 609 (4.0) | 1127 (7.4) | 1736 (5.7) |
| Number of Unsolicited Adverse Events | 975 | 1844 | 2819 |
| Infections and infestations | 15 (<0.1) | 9 (<0.1) | 24 (<0.1) |
| Injection site cellulitis | 0 | 2 (<0.1) | 2 (<0.1) |
| Viral infection | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| COVID-19 | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Conjunctivitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Ear infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Herpes zoster | 0 | 1 (<0.1) | 1 (<0.1) |
| Sinusitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Cellulitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Gingivitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Mastoiditis | 1 (<0.1) | 0 | 1 (<0.1) |
| Onychomycosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Oral herpes | 1 (<0.1) | 0 | 1 (<0.1) |
| Rhinitis | 2 (<0.1) | 0 | 2 (<0.1) |
| Tinea pedis | 1 (<0.1) | 0 | 1 (<0.1) |
| Upper respiratory tract infection | 4 (<0.1) | 0 | 4 (<0.1) |
| Varicella zoster virus infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Blood and lymphatic system disorders | 38 (0.3) | 73 (0.5) | 111 (0.4) |
| Lymphadenopathy | 35 (0.2) | 66 (0.4) | 101 (0.3) |

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MedDRA version 23.0.

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Table 14.3.1.11.1

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Blood and lymphatic system disorders (Cont.) | | | |
| Lymphadenitis | 0 | 5 (<0.1) | 5 (<0.1) |
| Lymph node pain | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |
| Anaemia | 0 | 1 (<0.1) | 1 (<0.1) |
| Immune system disorders | 0 | 2 (<0.1) | 2 (<0.1) |
| Seasonal allergy | 0 | 1 (<0.1) | 1 (<0.1) |
| Type IV hypersensitivity reaction | 0 | 1 (<0.1) | 1 (<0.1) |
| Metabolism and nutrition disorders | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Decreased appetite | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Abnormal loss of weight | 0 | 1 (<0.1) | 1 (<0.1) |
| Diabetes mellitus | 0 | 1 (<0.1) | 1 (<0.1) |
| Hyperglycaemia | 0 | 1 (<0.1) | 1 (<0.1) |
| Psychiatric disorders | 0 | 11 (<0.1) | 11 (<0.1) |
| Insomnia | 0 | 4 (<0.1) | 4 (<0.1) |
| Abnormal dreams | 0 | 3 (<0.1) | 3 (<0.1) |
| Sleep disorder | 0 | 2 (<0.1) | 2 (<0.1) |
| Affect lability | 0 | 1 (<0.1) | 1 (<0.1) |
| Hallucination | 0 | 1 (<0.1) | 1 (<0.1) |
| Nightmare | 0 | 1 (<0.1) | 1 (<0.1) |
| Nervous system disorders | 160 (1.1) | 258 (1.7) | 418 (1.4) |
| Headache | 122 (0.8) | 191 (1.3) | 313 (1.0) |

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Table 14.3.1.11.1

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Nervous system disorders (Cont.) | | | |
| Dizziness | 12 (<0.1) | 23 (0.2) | 35 (0.1) |
| Dysgeusia | 6 (<0.1) | 10 (<0.1) | 16 (<0.1) |
| Paraesthesia | 5 (<0.1) | 9 (<0.1) | 14 (<0.1) |
| Hyperaesthesia | 0 | 5 (<0.1) | 5 (<0.1) |
| Hypoaesthesia | 0 | 4 (<0.1) | 4 (<0.1) |
| Ageusia | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Somnolence | 0 | 2 (<0.1) | 2 (<0.1) |
| Syncope | 0 | 2 (<0.1) | 2 (<0.1) |
| Balance disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Burning sensation | 0 | 1 (<0.1) | 1 (<0.1) |
| Cervical radiculopathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Disturbance in attention | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Essential tremor | 0 | 1 (<0.1) | 1 (<0.1) |
| Idiopathic intracranial hypertension | 0 | 1 (<0.1) | 1 (<0.1) |
| Mental impairment | 0 | 1 (<0.1) | 1 (<0.1) |
| Migraine | 7 (<0.1) | 1 (<0.1) | 8 (<0.1) |
| Movement disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Neuralgia | 0 | 1 (<0.1) | 1 (<0.1) |
| Parosmia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Peripheral sensory neuropathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Poor quality sleep | 0 | 1 (<0.1) | 1 (<0.1) |
| Presyncope | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Sinus headache | 0 | 1 (<0.1) | 1 (<0.1) |
| Taste disorder | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |

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Table 14.3.1.11.1

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Nervous system disorders (Cont.) | | | |
| Anosmia | 1 (<0.1) | 0 | 1 (<0.1) |
| Dysaesthesia | 1 (<0.1) | 0 | 1 (<0.1) |
| Hypogeusia | 2 (<0.1) | 0 | 2 (<0.1) |
| Hyposmia | 1 (<0.1) | 0 | 1 (<0.1) |
| Sciatica | 1 (<0.1) | 0 | 1 (<0.1) |
| Eye disorders | 3 (<0.1) | 5 (<0.1) | 8 (<0.1) |
| Visual impairment | 0 | 2 (<0.1) | 2 (<0.1) |
| Blepharospasm | 0 | 1 (<0.1) | 1 (<0.1) |
| Eye irritation | 0 | 1 (<0.1) | 1 (<0.1) |
| Vitreous floaters | 0 | 1 (<0.1) | 1 (<0.1) |
| Eye swelling | 1 (<0.1) | 0 | 1 (<0.1) |
| Periorbital pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Visual acuity reduced | 1 (<0.1) | 0 | 1 (<0.1) |
| Ear and labyrinth disorders | 3 (<0.1) | 8 (<0.1) | 11 (<0.1) |
| Tinnitus | 1 (<0.1) | 5 (<0.1) | 6 (<0.1) |
| Ear discomfort | 0 | 1 (<0.1) | 1 (<0.1) |
| Vertigo | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Vertigo positional | 0 | 1 (<0.1) | 1 (<0.1) |
| Ear pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Cardiac disorders | 5 (<0.1) | 6 (<0.1) | 11 (<0.1) |
| Tachycardia | 0 | 4 (<0.1) | 4 (<0.1) |

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Table 14.3.1.11.1

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Cardiac disorders (Cont.) | | | |
| Sinus tachycardia | 0 | 2 (<0.1) | 2 (<0.1) |
| Arrhythmia | 2 (<0.1) | 0 | 2 (<0.1) |
| Bradycardia | 1 (<0.1) | 0 | 1 (<0.1) |
| Palpitations | 2 (<0.1) | 0 | 2 (<0.1) |
| Vascular disorders | 15 (<0.1) | 21 (0.1) | 36 (0.1) |
| Hypertension | 12 (<0.1) | 8 (<0.1) | 20 (<0.1) |
| Flushing | 1 (<0.1) | 6 (<0.1) | 7 (<0.1) |
| Hot flush | 2 (<0.1) | 5 (<0.1) | 7 (<0.1) |
| Deep vein thrombosis | 0 | 1 (<0.1) | 1 (<0.1) |
| Peripheral coldness | 0 | 1 (<0.1) | 1 (<0.1) |
| Respiratory, thoracic and mediastinal disorders | 36 (0.2) | 47 (0.3) | 83 (0.3) |
| Nasal congestion | 6 (<0.1) | 18 (0.1) | 24 (<0.1) |
| Cough | 4 (<0.1) | 12 (<0.1) | 16 (<0.1) |
| Rhinorrhoea | 9 (<0.1) | 11 (<0.1) | 20 (<0.1) |
| Oropharyngeal pain | 13 (<0.1) | 10 (<0.1) | 23 (<0.1) |
| Dyspnoea | 2 (<0.1) | 5 (<0.1) | 7 (<0.1) |
| Throat irritation | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |
| Asthma | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Sinus congestion | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Sinus pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Chronic obstructive pulmonary disease | 1 (<0.1) | 0 | 1 (<0.1) |
| Dysphonia | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.11.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Respiratory, thoracic and mediastinal disorders (Cont.) | | | |
| Paranasal sinus discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Pleurisy | 1 (<0.1) | 0 | 1 (<0.1) |
| Productive cough | 2 (<0.1) | 0 | 2 (<0.1) |
| Pulmonary embolism | 1 (<0.1) | 0 | 1 (<0.1) |
| Tachypnoea | 1 (<0.1) | 0 | 1 (<0.1) |
| Tonsillar inflammation | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastrointestinal disorders | 67 (0.4) | 74 (0.5) | 141 (0.5) |
| Diarrhoea | 24 (0.2) | 36 (0.2) | 60 (0.2) |
| Nausea | 32 (0.2) | 26 (0.2) | 58 (0.2) |
| Abdominal pain | 1 (<0.1) | 6 (<0.1) | 7 (<0.1) |
| Vomiting | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |
| Chapped lips | 0 | 2 (<0.1) | 2 (<0.1) |
| Lip swelling | 0 | 2 (<0.1) | 2 (<0.1) |
| Swollen tongue | 0 | 2 (<0.1) | 2 (<0.1) |
| Toothache | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Abdominal discomfort | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Abdominal pain upper | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Aphthous ulcer | 0 | 1 (<0.1) | 1 (<0.1) |
| Dry mouth | 0 | 1 (<0.1) | 1 (<0.1) |
| Dyspepsia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Gastrooesophageal reflux disease | 0 | 1 (<0.1) | 1 (<0.1) |
| Hyperaesthesia teeth | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |

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Table 14.3.1.11.1

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Gastrointestinal disorders (Cont.) | | | |
| Tooth discolouration | 0 | 1 (<0.1) | 1 (<0.1) |
| Dysphagia | 1 (<0.1) | 0 | 1 (<0.1) |
| Gingival discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Gingival pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Irritable bowel syndrome | 1 (<0.1) | 0 | 1 (<0.1) |
| Paraesthesia oral | 3 (<0.1) | 0 | 3 (<0.1) |
| Salivary hypersecretion | 1 (<0.1) | 0 | 1 (<0.1) |
| Skin and subcutaneous tissue disorders | 29 (0.2) | 66 (0.4) | 95 (0.3) |
| Rash | 7 (<0.1) | 13 (<0.1) | 20 (<0.1) |
| Urticaria | 1 (<0.1) | 11 (<0.1) | 12 (<0.1) |
| Pruritus | 9 (<0.1) | 8 (<0.1) | 17 (<0.1) |
| Hyperhidrosis | 4 (<0.1) | 7 (<0.1) | 11 (<0.1) |
| Night sweats | 4 (<0.1) | 6 (<0.1) | 10 (<0.1) |
| Erythema | 0 | 5 (<0.1) | 5 (<0.1) |
| Skin burning sensation | 0 | 3 (<0.1) | 3 (<0.1) |
| Alopecia | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Dermatitis | 0 | 2 (<0.1) | 2 (<0.1) |
| Psoriasis | 0 | 2 (<0.1) | 2 (<0.1) |
| Rash pruritic | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Acne | 0 | 1 (<0.1) | 1 (<0.1) |
| Angioedema | 0 | 1 (<0.1) | 1 (<0.1) |
| Macule | 0 | 1 (<0.1) | 1 (<0.1) |
| Pityriasis rosea | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.11.1

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Skin and subcutaneous tissue disorders (Cont.) | | | |
| Rash erythematous | 0 | 1 (<0.1) | 1 (<0.1) |
| Skin warm | 0 | 1 (<0.1) | 1 (<0.1) |
| Dermatitis bullous | 1 (<0.1) | 0 | 1 (<0.1) |
| Dermatitis contact | 1 (<0.1) | 0 | 1 (<0.1) |
| Ecchymosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Skin discolouration | 1 (<0.1) | 0 | 1 (<0.1) |
| Musculoskeletal and connective tissue disorders | 129 (0.9) | 193 (1.3) | 322 (1.1) |
| Myalgia | 57 (0.4) | 95 (0.6) | 152 (0.5) |
| Arthralgia | 75 (0.5) | 80 (0.5) | 155 (0.5) |
| Pain in extremity | 8 (<0.1) | 16 (0.1) | 24 (<0.1) |
| Neck pain | 2 (<0.1) | 9 (<0.1) | 11 (<0.1) |
| Back pain | 2 (<0.1) | 8 (<0.1) | 10 (<0.1) |
| Musculoskeletal pain | 6 (<0.1) | 6 (<0.1) | 12 (<0.1) |
| Muscle spasms | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |
| Joint range of motion decreased | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Limb discomfort | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Bone pain | 0 | 2 (<0.1) | 2 (<0.1) |
| Muscular weakness | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Tendonitis | 0 | 2 (<0.1) | 2 (<0.1) |
| Arthropathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Axillary mass | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Bone lesion | 0 | 1 (<0.1) | 1 (<0.1) |
| Bone swelling | 0 | 1 (<0.1) | 1 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.11.1

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Musculoskeletal and connective tissue disorders (Cont.) | | | |
| Costochondritis | 0 | 1 (<0.1) | 1 (<0.1) |
| Flank pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Joint stiffness | 0 | 1 (<0.1) | 1 (<0.1) |
| Musculoskeletal chest pain | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Musculoskeletal stiffness | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Neck mass | 0 | 1 (<0.1) | 1 (<0.1) |
| Osteoarthritis | 0 | 1 (<0.1) | 1 (<0.1) |
| Polyarthritis | 0 | 1 (<0.1) | 1 (<0.1) |
| Rheumatoid arthritis | 0 | 1 (<0.1) | 1 (<0.1) |
| Temporomandibular joint syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Muscle tightness | 1 (<0.1) | 0 | 1 (<0.1) |
| Muscle twitching | 1 (<0.1) | 0 | 1 (<0.1) |
| Musculoskeletal discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Polymyalgia rheumatica | 1 (<0.1) | 0 | 1 (<0.1) |
| Reproductive system and breast disorders | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Menorrhagia | 0 | 2 (<0.1) | 2 (<0.1) |
| Erectile dysfunction | 0 | 1 (<0.1) | 1 (<0.1) |
| Breast pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Dysmenorrhoea | 1 (<0.1) | 0 | 1 (<0.1) |
| Menstruation irregular | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.11.1

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| General disorders and administration site conditions | 277 (1.8) | 579 (3.8) | 856 (2.8) |
| Fatigue | 159 (1.0) | 198 (1.3) | 357 (1.2) |
| Injection site pain | 34 (0.2) | 111 (0.7) | 145 (0.5) |
| Injection site erythema | 12 (<0.1) | 89 (0.6) | 101 (0.3) |
| Injection site swelling | 12 (<0.1) | 60 (0.4) | 72 (0.2) |
| Injection site pruritus | 11 (<0.1) | 53 (0.3) | 64 (0.2) |
| Chills | 13 (<0.1) | 39 (0.3) | 52 (0.2) |
| Injection site induration | 7 (<0.1) | 30 (0.2) | 37 (0.1) |
| Pyrexia | 8 (<0.1) | 29 (0.2) | 37 (0.1) |
| Injection site rash | 1 (<0.1) | 25 (0.2) | 26 (<0.1) |
| Axillary pain | 3 (<0.1) | 19 (0.1) | 22 (<0.1) |
| Pain | 6 (<0.1) | 18 (0.1) | 24 (<0.1) |
| Swelling | 4 (<0.1) | 8 (<0.1) | 12 (<0.1) |
| Malaise | 4 (<0.1) | 7 (<0.1) | 11 (<0.1) |
| Injection site lymphadenopathy | 1 (<0.1) | 6 (<0.1) | 7 (<0.1) |
| Injection site urticaria | 0 | 5 (<0.1) | 5 (<0.1) |
| Injection site warmth | 1 (<0.1) | 5 (<0.1) | 6 (<0.1) |
| Injection site haemorrhage | 1 (<0.1) | 4 (<0.1) | 5 (<0.1) |
| Reactogenicity event | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |
| Vaccination site lymphadenopathy | 0 | 4 (<0.1) | 4 (<0.1) |
| Chest discomfort | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Injection site bruising | 9 (<0.1) | 3 (<0.1) | 12 (<0.1) |
| Injection site reaction | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Tenderness | 0 | 3 (<0.1) | 3 (<0.1) |

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Table 14.3.1.11.1

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| General disorders and administration site conditions (Cont.) | | | |
| Vaccination site erythema | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Induration | 0 | 2 (<0.1) | 2 (<0.1) |
| Injection site irritation | 0 | 2 (<0.1) | 2 (<0.1) |
| Injection site joint pain | 0 | 2 (<0.1) | 2 (<0.1) |
| Injection site nodule | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Peripheral swelling | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Swelling face | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Vaccination site swelling | 0 | 2 (<0.1) | 2 (<0.1) |
| Adverse drug reaction | 0 | 1 (<0.1) | 1 (<0.1) |
| Chest pain | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Facial discomfort | 0 | 1 (<0.1) | 1 (<0.1) |
| Feeling hot | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Influenza like illness | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site haematoma | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Injection site paraesthesia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Injection site scab | 0 | 1 (<0.1) | 1 (<0.1) |
| Non-cardiac chest pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Oedema peripheral | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaccination site induration | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaccination site pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaccination site pruritus | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaccination site rash | 0 | 1 (<0.1) | 1 (<0.1) |
| Asthenia | 4 (<0.1) | 0 | 4 (<0.1) |

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Table 14.3.1.11.1

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| General disorders and administration site conditions (Cont.) | | | |
| Discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Feeling abnormal | 1 (<0.1) | 0 | 1 (<0.1) |
| Injection site discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Injection site mass | 1 (<0.1) | 0 | 1 (<0.1) |
| Vaccination site nodule | 1 (<0.1) | 0 | 1 (<0.1) |
| Investigations | 5 (<0.1) | 14 (<0.1) | 19 (<0.1) |
| Blood pressure increased | 3 (<0.1) | 5 (<0.1) | 8 (<0.1) |
| Blood pressure diastolic increased | 0 | 2 (<0.1) | 2 (<0.1) |
| Blood pressure systolic increased | 0 | 2 (<0.1) | 2 (<0.1) |
| Body temperature increased | 0 | 2 (<0.1) | 2 (<0.1) |
| Heart rate increased | 0 | 2 (<0.1) | 2 (<0.1) |
| Heart rate irregular | 0 | 1 (<0.1) | 1 (<0.1) |
| Respiratory rate increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Blood glucose increased | 1 (<0.1) | 0 | 1 (<0.1) |
| Hepatic enzyme increased | 1 (<0.1) | 0 | 1 (<0.1) |
| Injury, poisoning and procedural complications | 6 (<0.1) | 5 (<0.1) | 11 (<0.1) |
| Contusion | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Injection related reaction | 0 | 1 (<0.1) | 1 (<0.1) |
| Procedural headache | 0 | 1 (<0.1) | 1 (<0.1) |
| Tooth fracture | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Vaccination complication | 0 | 1 (<0.1) | 1 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.11.1

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Injury, poisoning and procedural complications (Cont.) | | | |
| Fall | 1 (<0.1) | 0 | 1 (<0.1) |
| Immunisation anxiety related reaction | 1 (<0.1) | 0 | 1 (<0.1) |
| Ulnar nerve injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Surgical and medical procedures | 0 | 2 (<0.1) | 2 (<0.1) |
| Axillary lymphadenectomy | 0 | 2 (<0.1) | 2 (<0.1) |
| Uncoded | 34 (0.2) | 125 (0.8) | 159 (0.5) |
| Uncoded | 34 (0.2) | 125 (0.8) | 159 (0.5) |

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Number of Subjects Reporting Unsolicited Adverse Events | 471 (4.1) | 866 (7.6) | 1337 (5.9) |
| Number of Unsolicited Adverse Events | 754 | 1421 | 2175 |
| Infections and infestations | 12 (0.1) | 6 (<0.1) | 18 (<0.1) |
| Injection site cellulitis | 0 | 2 (<0.1) | 2 (<0.1) |
| Viral infection | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Ear infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Sinusitis | 0 | 1 (<0.1) | 1 (<0.1) |
| COVID-19 | 1 (<0.1) | 0 | 1 (<0.1) |
| Gingivitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Mastoiditis | 1 (<0.1) | 0 | 1 (<0.1) |
| Onychomycosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Rhinitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Tinea pedis | 1 (<0.1) | 0 | 1 (<0.1) |
| Upper respiratory tract infection | 4 (<0.1) | 0 | 4 (<0.1) |
| Varicella zoster virus infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Blood and lymphatic system disorders | 35 (0.3) | 64 (0.6) | 99 (0.4) |
| Lymphadenopathy | 33 (0.3) | 57 (0.5) | 90 (0.4) |
| Lymphadenitis | 0 | 5 (<0.1) | 5 (<0.1) |
| Lymph node pain | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t1403011102.sas 18NOV2020 06:19

Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Blood and lymphatic system disorders (Cont.) | | | |
| Anaemia | 0 | 1 (<0.1) | 1 (<0.1) |
| Immune system disorders | 0 | 1 (<0.1) | 1 (<0.1) |
| Seasonal allergy | 0 | 1 (<0.1) | 1 (<0.1) |
| Metabolism and nutrition disorders | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Decreased appetite | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Abnormal loss of weight | 0 | 1 (<0.1) | 1 (<0.1) |
| Diabetes mellitus | 0 | 1 (<0.1) | 1 (<0.1) |
| Hyperglycaemia | 0 | 1 (<0.1) | 1 (<0.1) |
| Psychiatric disorders | 0 | 8 (<0.1) | 8 (<0.1) |
| Insomnia | 0 | 4 (<0.1) | 4 (<0.1) |
| Abnormal dreams | 0 | 3 (<0.1) | 3 (<0.1) |
| Affect lability | 0 | 1 (<0.1) | 1 (<0.1) |
| Sleep disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Nervous system disorders | 127 (1.1) | 200 (1.8) | 327 (1.4) |
| Headache | 99 (0.9) | 148 (1.3) | 247 (1.1) |
| Dizziness | 8 (<0.1) | 15 (0.1) | 23 (0.1) |
| Dysgeusia | 3 (<0.1) | 9 (<0.1) | 12 (<0.1) |
| Paraesthesia | 5 (<0.1) | 9 (<0.1) | 14 (<0.1) |

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Nervous system disorders (Cont.) | | | |
| Hyperaesthesia | 0 | 4 (<0.1) | 4 (<0.1) |
| Ageusia | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Hypoaesthesia | 0 | 2 (<0.1) | 2 (<0.1) |
| Somnolence | 0 | 2 (<0.1) | 2 (<0.1) |
| Syncope | 0 | 2 (<0.1) | 2 (<0.1) |
| Burning sensation | 0 | 1 (<0.1) | 1 (<0.1) |
| Disturbance in attention | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Idiopathic intracranial hypertension | 0 | 1 (<0.1) | 1 (<0.1) |
| Mental impairment | 0 | 1 (<0.1) | 1 (<0.1) |
| Migraine | 6 (<0.1) | 1 (<0.1) | 7 (<0.1) |
| Movement disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Parosmia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Peripheral sensory neuropathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Presyncope | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Taste disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Anosmia | 1 (<0.1) | 0 | 1 (<0.1) |
| Hypogeusia | 2 (<0.1) | 0 | 2 (<0.1) |
| Hyposmia | 1 (<0.1) | 0 | 1 (<0.1) |
| Sciatica | 1 (<0.1) | 0 | 1 (<0.1) |
| Eye disorders | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Blepharospasm | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Eye disorders (Cont.) | | | |
| Visual impairment | 0 | 1 (<0.1) | 1 (<0.1) |
| Vitreous floaters | 0 | 1 (<0.1) | 1 (<0.1) |
| Eye swelling | 1 (<0.1) | 0 | 1 (<0.1) |
| Periorbital pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Visual acuity reduced | 1 (<0.1) | 0 | 1 (<0.1) |
| Ear and labyrinth disorders | 2 (<0.1) | 5 (<0.1) | 7 (<0.1) |
| Tinnitus | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Ear discomfort | 0 | 1 (<0.1) | 1 (<0.1) |
| Vertigo | 0 | 1 (<0.1) | 1 (<0.1) |
| Ear pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Cardiac disorders | 2 (<0.1) | 5 (<0.1) | 7 (<0.1) |
| Tachycardia | 0 | 4 (<0.1) | 4 (<0.1) |
| Sinus tachycardia | 0 | 1 (<0.1) | 1 (<0.1) |
| Arrhythmia | 1 (<0.1) | 0 | 1 (<0.1) |
| Palpitations | 1 (<0.1) | 0 | 1 (<0.1) |
| Vascular disorders | 7 (<0.1) | 13 (0.1) | 20 (<0.1) |
| Flushing | 1 (<0.1) | 4 (<0.1) | 5 (<0.1) |
| Hypertension | 5 (<0.1) | 4 (<0.1) | 9 (<0.1) |
| Hot flush | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |

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MedDRA version 23.0.

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Vascular disorders (Cont.) | | | |
| Deep vein thrombosis | 0 | 1 (<0.1) | 1 (<0.1) |
| Peripheral coldness | 0 | 1 (<0.1) | 1 (<0.1) |
| Respiratory, thoracic and mediastinal disorders | 27 (0.2) | 40 (0.4) | 67 (0.3) |
| Nasal congestion | 4 (<0.1) | 16 (0.1) | 20 (<0.1) |
| Cough | 4 (<0.1) | 11 (<0.1) | 15 (<0.1) |
| Rhinorrhoea | 5 (<0.1) | 8 (<0.1) | 13 (<0.1) |
| Oropharyngeal pain | 11 (<0.1) | 6 (<0.1) | 17 (<0.1) |
| Dyspnoea | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Throat irritation | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Asthma | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Sinus congestion | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Sinus pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Chronic obstructive pulmonary disease | 1 (<0.1) | 0 | 1 (<0.1) |
| Paranasal sinus discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Pleurisy | 1 (<0.1) | 0 | 1 (<0.1) |
| Productive cough | 1 (<0.1) | 0 | 1 (<0.1) |
| Pulmonary embolism | 1 (<0.1) | 0 | 1 (<0.1) |
| Tonsillar inflammation | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastrointestinal disorders | 48 (0.4) | 58 (0.5) | 106 (0.5) |
| Diarrhoea | 15 (0.1) | 29 (0.3) | 44 (0.2) |

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Percentages are based on the number of safety subjects.

MedDRA version 23.0.

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Gastrointestinal disorders (Cont.) | | | |
| Nausea | 25 (0.2) | 21 (0.2) | 46 (0.2) |
| Abdominal pain | 1 (<0.1) | 4 (<0.1) | 5 (<0.1) |
| Vomiting | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Chapped lips | 0 | 2 (<0.1) | 2 (<0.1) |
| Toothache | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Abdominal discomfort | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Aphthous ulcer | 0 | 1 (<0.1) | 1 (<0.1) |
| Dry mouth | 0 | 1 (<0.1) | 1 (<0.1) |
| Gastroesophageal reflux disease | 0 | 1 (<0.1) | 1 (<0.1) |
| Hyperaesthesia teeth | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Lip swelling | 0 | 1 (<0.1) | 1 (<0.1) |
| Swollen tongue | 0 | 1 (<0.1) | 1 (<0.1) |
| Abdominal pain upper | 1 (<0.1) | 0 | 1 (<0.1) |
| Dyspepsia | 1 (<0.1) | 0 | 1 (<0.1) |
| Dysphagia | 1 (<0.1) | 0 | 1 (<0.1) |
| Gingival discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Irritable bowel syndrome | 1 (<0.1) | 0 | 1 (<0.1) |
| Paraesthesia oral | 2 (<0.1) | 0 | 2 (<0.1) |
| Skin and subcutaneous tissue disorders | 21 (0.2) | 47 (0.4) | 68 (0.3) |
| Rash | 7 (<0.1) | 10 (<0.1) | 17 (<0.1) |
| Urticaria | 0 | 8 (<0.1) | 8 (<0.1) |

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Skin and subcutaneous tissue disorders (Cont.) | | | |
| Night sweats | 2 (<0.1) | 5 (<0.1) | 7 (<0.1) |
| Hyperhidrosis | 4 (<0.1) | 4 (<0.1) | 8 (<0.1) |
| Pruritus | 6 (<0.1) | 4 (<0.1) | 10 (<0.1) |
| Erythema | 0 | 3 (<0.1) | 3 (<0.1) |
| Skin burning sensation | 0 | 3 (<0.1) | 3 (<0.1) |
| Alopecia | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Psoriasis | 0 | 2 (<0.1) | 2 (<0.1) |
| Acne | 0 | 1 (<0.1) | 1 (<0.1) |
| Angioedema | 0 | 1 (<0.1) | 1 (<0.1) |
| Dermatitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Macule | 0 | 1 (<0.1) | 1 (<0.1) |
| Pityriasis rosea | 0 | 1 (<0.1) | 1 (<0.1) |
| Rash erythematous | 0 | 1 (<0.1) | 1 (<0.1) |
| Skin warm | 0 | 1 (<0.1) | 1 (<0.1) |
| Dermatitis bullous | 1 (<0.1) | 0 | 1 (<0.1) |
| Rash pruritic | 1 (<0.1) | 0 | 1 (<0.1) |
| Skin discolouration | 1 (<0.1) | 0 | 1 (<0.1) |
| Musculoskeletal and connective tissue disorders | 100 (0.9) | 146 (1.3) | 246 (1.1) |
| Myalgia | 44 (0.4) | 71 (0.6) | 115 (0.5) |
| Arthralgia | 59 (0.5) | 61 (0.5) | 120 (0.5) |
| Pain in extremity | 6 (<0.1) | 11 (<0.1) | 17 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Musculoskeletal and connective tissue disorders (Cont.) | | | |
| Neck pain | 2 (<0.1) | 8 (<0.1) | 10 (<0.1) |
| Back pain | 1 (<0.1) | 6 (<0.1) | 7 (<0.1) |
| Musculoskeletal pain | 5 (<0.1) | 6 (<0.1) | 11 (<0.1) |
| Limb discomfort | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Bone pain | 0 | 2 (<0.1) | 2 (<0.1) |
| Joint range of motion decreased | 0 | 2 (<0.1) | 2 (<0.1) |
| Muscle spasms | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Tendonitis | 0 | 2 (<0.1) | 2 (<0.1) |
| Arthropathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Axillary mass | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Bone lesion | 0 | 1 (<0.1) | 1 (<0.1) |
| Bone swelling | 0 | 1 (<0.1) | 1 (<0.1) |
| Costochondritis | 0 | 1 (<0.1) | 1 (<0.1) |
| Musculoskeletal chest pain | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Musculoskeletal stiffness | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Neck mass | 0 | 1 (<0.1) | 1 (<0.1) |
| Polyarthrititis | 0 | 1 (<0.1) | 1 (<0.1) |
| Rheumatoid arthritis | 0 | 1 (<0.1) | 1 (<0.1) |
| Temporomandibular joint syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Muscle tightness | 1 (<0.1) | 0 | 1 (<0.1) |
| Muscle twitching | 1 (<0.1) | 0 | 1 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Musculoskeletal and connective tissue disorders (Cont.) | | | |
| Muscular weakness | 1 (<0.1) | 0 | 1 (<0.1) |
| Musculoskeletal discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Reproductive system and breast disorders | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Menorrhagia | 0 | 2 (<0.1) | 2 (<0.1) |
| Breast pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Dysmenorrhoea | 1 (<0.1) | 0 | 1 (<0.1) |
| Menstruation irregular | 1 (<0.1) | 0 | 1 (<0.1) |
| General disorders and administration site conditions | 216 (1.9) | 448 (3.9) | 664 (2.9) |
| Fatigue | 131 (1.1) | 145 (1.3) | 276 (1.2) |
| Injection site pain | 26 (0.2) | 93 (0.8) | 119 (0.5) |
| Injection site erythema | 5 (<0.1) | 60 (0.5) | 65 (0.3) |
| Injection site swelling | 7 (<0.1) | 50 (0.4) | 57 (0.2) |
| Injection site pruritus | 9 (<0.1) | 39 (0.3) | 48 (0.2) |
| Chills | 10 (<0.1) | 34 (0.3) | 44 (0.2) |
| Injection site induration | 4 (<0.1) | 26 (0.2) | 30 (0.1) |
| Pyrexia | 7 (<0.1) | 24 (0.2) | 31 (0.1) |
| Injection site rash | 1 (<0.1) | 18 (0.2) | 19 (<0.1) |
| Axillary pain | 2 (<0.1) | 16 (0.1) | 18 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| General disorders and administration site conditions (Cont.) | | | |
| Pain | 6 (<0.1) | 14 (0.1) | 20 (<0.1) |
| Swelling | 3 (<0.1) | 8 (<0.1) | 11 (<0.1) |
| Malaise | 2 (<0.1) | 7 (<0.1) | 9 (<0.1) |
| Injection site lymphadenopathy | 1 (<0.1) | 5 (<0.1) | 6 (<0.1) |
| Injection site urticaria | 0 | 4 (<0.1) | 4 (<0.1) |
| Chest discomfort | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Injection site haemorrhage | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Injection site warmth | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Reactogenicity event | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Tenderness | 0 | 3 (<0.1) | 3 (<0.1) |
| Vaccination site erythema | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Vaccination site lymphadenopathy | 0 | 3 (<0.1) | 3 (<0.1) |
| Induration | 0 | 2 (<0.1) | 2 (<0.1) |
| Injection site bruising | 6 (<0.1) | 2 (<0.1) | 8 (<0.1) |
| Injection site irritation | 0 | 2 (<0.1) | 2 (<0.1) |
| Injection site nodule | 0 | 2 (<0.1) | 2 (<0.1) |
| Injection site reaction | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Peripheral swelling | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Swelling face | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Vaccination site swelling | 0 | 2 (<0.1) | 2 (<0.1) |
| Adverse drug reaction | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| General disorders and administration site conditions (Cont.) | | | |
| Chest pain | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Facial discomfort | 0 | 1 (<0.1) | 1 (<0.1) |
| Influenza like illness | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site haematoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site joint pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site paraesthesia | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site scab | 0 | 1 (<0.1) | 1 (<0.1) |
| Non-cardiac chest pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaccination site induration | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaccination site pruritus | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaccination site rash | 0 | 1 (<0.1) | 1 (<0.1) |
| Asthenia | 3 (<0.1) | 0 | 3 (<0.1) |
| Discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Feeling abnormal | 1 (<0.1) | 0 | 1 (<0.1) |
| Feeling hot | 1 (<0.1) | 0 | 1 (<0.1) |
| Injection site discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Vaccination site nodule | 1 (<0.1) | 0 | 1 (<0.1) |
| Investigations | 3 (<0.1) | 9 (<0.1) | 12 (<0.1) |
| Blood pressure increased | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Body temperature increased | 0 | 2 (<0.1) | 2 (<0.1) |

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Age Group: >=18 and <65 Years

| System Organ Class Preferred Term | Placebo (N=11415) n (%) | mRNA-1273 (N=11414) n (%) | Total (N=22830) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Investigations (Cont.) | | | |
| Blood pressure diastolic increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Blood pressure systolic increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Heart rate increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Heart rate irregular | 0 | 1 (<0.1) | 1 (<0.1) |
| Respiratory rate increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Hepatic enzyme increased | 1 (<0.1) | 0 | 1 (<0.1) |
| Injury, poisoning and procedural complications | 4 (<0.1) | 4 (<0.1) | 8 (<0.1) |
| Contusion | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Injection related reaction | 0 | 1 (<0.1) | 1 (<0.1) |
| Procedural headache | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaccination complication | 0 | 1 (<0.1) | 1 (<0.1) |
| Immunisation anxiety related reaction | 1 (<0.1) | 0 | 1 (<0.1) |
| Tooth fracture | 1 (<0.1) | 0 | 1 (<0.1) |
| Surgical and medical procedures | 0 | 2 (<0.1) | 2 (<0.1) |
| Axillary lymphadenectomy | 0 | 2 (<0.1) | 2 (<0.1) |
| Uncoded | 31 (0.3) | 98 (0.9) | 129 (0.6) |
| Uncoded | 31 (0.3) | 98 (0.9) | 129 (0.6) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|---|------------------------------|--------------------------------|----------------------------|
| Number of Subjects Reporting Unsolicited Adverse Events | 138 (3.7) | 261 (6.9) | 399 (5.3) |
| Number of Unsolicited Adverse Events | 221 | 423 | 644 |
| Infections and infestations | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| COVID-19 | 0 | 1 (<0.1) | 1 (<0.1) |
| Conjunctivitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Herpes zoster | 0 | 1 (<0.1) | 1 (<0.1) |
| Cellulitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Oral herpes | 1 (<0.1) | 0 | 1 (<0.1) |
| Rhinitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Blood and lymphatic system disorders | 3 (<0.1) | 9 (0.2) | 12 (0.2) |
| Lymphadenopathy | 2 (<0.1) | 9 (0.2) | 11 (0.1) |
| Lymph node pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Immune system disorders | 0 | 1 (<0.1) | 1 (<0.1) |
| Type IV hypersensitivity reaction | 0 | 1 (<0.1) | 1 (<0.1) |
| Psychiatric disorders | 0 | 3 (<0.1) | 3 (<0.1) |
| Hallucination | 0 | 1 (<0.1) | 1 (<0.1) |
| Nightmare | 0 | 1 (<0.1) | 1 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--------------------------------------|------------------------------|--------------------------------|----------------------------|
| Psychiatric disorders (Cont.) | | | |
| Sleep disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Nervous system disorders | 33 (0.9) | 58 (1.5) | 91 (1.2) |
| Headache | 23 (0.6) | 43 (1.1) | 66 (0.9) |
| Dizziness | 4 (0.1) | 8 (0.2) | 12 (0.2) |
| Hypoaesthesia | 0 | 2 (<0.1) | 2 (<0.1) |
| Balance disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Cervical radiculopathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Dysgeusia | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Essential tremor | 0 | 1 (<0.1) | 1 (<0.1) |
| Hyperaesthesia | 0 | 1 (<0.1) | 1 (<0.1) |
| Neuralgia | 0 | 1 (<0.1) | 1 (<0.1) |
| Poor quality sleep | 0 | 1 (<0.1) | 1 (<0.1) |
| Sinus headache | 0 | 1 (<0.1) | 1 (<0.1) |
| Dysaesthesia | 1 (<0.1) | 0 | 1 (<0.1) |
| Migraine | 1 (<0.1) | 0 | 1 (<0.1) |
| Taste disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Eye disorders | 0 | 2 (<0.1) | 2 (<0.1) |
| Eye irritation | 0 | 1 (<0.1) | 1 (<0.1) |
| Visual impairment | 0 | 1 (<0.1) | 1 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|---|------------------------------|--------------------------------|----------------------------|
| Ear and labyrinth disorders | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Tinnitus | 0 | 2 (<0.1) | 2 (<0.1) |
| Vertigo positional | 0 | 1 (<0.1) | 1 (<0.1) |
| Vertigo | 1 (<0.1) | 0 | 1 (<0.1) |
| Cardiac disorders | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Sinus tachycardia | 0 | 1 (<0.1) | 1 (<0.1) |
| Arrhythmia | 1 (<0.1) | 0 | 1 (<0.1) |
| Bradycardia | 1 (<0.1) | 0 | 1 (<0.1) |
| Palpitations | 1 (<0.1) | 0 | 1 (<0.1) |
| Vascular disorders | 8 (0.2) | 8 (0.2) | 16 (0.2) |
| Hypertension | 7 (0.2) | 4 (0.1) | 11 (0.1) |
| Flushing | 0 | 2 (<0.1) | 2 (<0.1) |
| Hot flush | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Respiratory, thoracic and mediastinal disorders | 9 (0.2) | 7 (0.2) | 16 (0.2) |
| Oropharyngeal pain | 2 (<0.1) | 4 (0.1) | 6 (<0.1) |
| Rhinorrhoea | 4 (0.1) | 3 (<0.1) | 7 (<0.1) |
| Nasal congestion | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Cough | 0 | 1 (<0.1) | 1 (<0.1) |
| Dyspnoea | 0 | 1 (<0.1) | 1 (<0.1) |
| Dysphonia | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--|------------------------------|--------------------------------|----------------------------|
| Respiratory, thoracic and mediastinal disorders (Cont.) | | | |
| Productive cough | 1 (<0.1) | 0 | 1 (<0.1) |
| Tachypnoea | 1 (<0.1) | 0 | 1 (<0.1) |
| Throat irritation | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastrointestinal disorders | 19 (0.5) | 16 (0.4) | 35 (0.5) |
| Diarrhoea | 9 (0.2) | 7 (0.2) | 16 (0.2) |
| Nausea | 7 (0.2) | 5 (0.1) | 12 (0.2) |
| Abdominal pain | 0 | 2 (<0.1) | 2 (<0.1) |
| Abdominal pain upper | 0 | 1 (<0.1) | 1 (<0.1) |
| Dyspepsia | 0 | 1 (<0.1) | 1 (<0.1) |
| Lip swelling | 0 | 1 (<0.1) | 1 (<0.1) |
| Swollen tongue | 0 | 1 (<0.1) | 1 (<0.1) |
| Tooth discolouration | 0 | 1 (<0.1) | 1 (<0.1) |
| Vomiting | 0 | 1 (<0.1) | 1 (<0.1) |
| Gingival pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Paraesthesia oral | 1 (<0.1) | 0 | 1 (<0.1) |
| Salivary hypersecretion | 1 (<0.1) | 0 | 1 (<0.1) |
| Skin and subcutaneous tissue disorders | 8 (0.2) | 19 (0.5) | 27 (0.4) |
| Pruritus | 3 (<0.1) | 4 (0.1) | 7 (<0.1) |
| Hyperhidrosis | 0 | 3 (<0.1) | 3 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|---|------------------------------|--------------------------------|----------------------------|
| Skin and subcutaneous tissue disorders (Cont.) | | | |
| Rash | 0 | 3 (<0.1) | 3 (<0.1) |
| Urticaria | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Erythema | 0 | 2 (<0.1) | 2 (<0.1) |
| Rash pruritic | 0 | 2 (<0.1) | 2 (<0.1) |
| Dermatitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Night sweats | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Dermatitis contact | 1 (<0.1) | 0 | 1 (<0.1) |
| Ecchymosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Musculoskeletal and connective tissue disorders | 29 (0.8) | 47 (1.2) | 76 (1.0) |
| Myalgia | 13 (0.3) | 24 (0.6) | 37 (0.5) |
| Arthralgia | 16 (0.4) | 19 (0.5) | 35 (0.5) |
| Pain in extremity | 2 (<0.1) | 5 (0.1) | 7 (<0.1) |
| Back pain | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Muscle spasms | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Muscular weakness | 0 | 2 (<0.1) | 2 (<0.1) |
| Flank pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Joint range of motion decreased | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Joint stiffness | 0 | 1 (<0.1) | 1 (<0.1) |
| Neck pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Osteoarthritis | 0 | 1 (<0.1) | 1 (<0.1) |
| Musculoskeletal pain | 1 (<0.1) | 0 | 1 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--|------------------------------|--------------------------------|----------------------------|
| Musculoskeletal and connective tissue disorders (Cont.) | | | |
| Musculoskeletal stiffness | 1 (<0.1) | 0 | 1 (<0.1) |
| Polymyalgia rheumatica | 1 (<0.1) | 0 | 1 (<0.1) |
| Reproductive system and breast disorders | 0 | 1 (<0.1) | 1 (<0.1) |
| Erectile dysfunction | 0 | 1 (<0.1) | 1 (<0.1) |
| General disorders and administration site conditions | 61 (1.6) | 131 (3.5) | 192 (2.6) |
| Fatigue | 28 (0.7) | 53 (1.4) | 81 (1.1) |
| Injection site erythema | 7 (0.2) | 29 (0.8) | 36 (0.5) |
| Injection site pain | 8 (0.2) | 18 (0.5) | 26 (0.3) |
| Injection site pruritus | 2 (<0.1) | 14 (0.4) | 16 (0.2) |
| Injection site swelling | 5 (0.1) | 10 (0.3) | 15 (0.2) |
| Injection site rash | 0 | 7 (0.2) | 7 (<0.1) |
| Chills | 3 (<0.1) | 5 (0.1) | 8 (0.1) |
| Pyrexia | 1 (<0.1) | 5 (0.1) | 6 (<0.1) |
| Injection site induration | 3 (<0.1) | 4 (0.1) | 7 (<0.1) |
| Pain | 0 | 4 (0.1) | 4 (<0.1) |
| Axillary pain | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Injection site warmth | 0 | 2 (<0.1) | 2 (<0.1) |
| Feeling hot | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--|------------------------------|--------------------------------|----------------------------|
| General disorders and administration site conditions (Cont.) | | | |
| Injection site bruising | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Injection site haemorrhage | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site joint pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site lymphadenopathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site reaction | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site urticaria | 0 | 1 (<0.1) | 1 (<0.1) |
| Oedema peripheral | 0 | 1 (<0.1) | 1 (<0.1) |
| Reactogenicity event | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaccination site lymphadenopathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaccination site pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Asthenia | 1 (<0.1) | 0 | 1 (<0.1) |
| Injection site haematoma | 1 (<0.1) | 0 | 1 (<0.1) |
| Injection site mass | 1 (<0.1) | 0 | 1 (<0.1) |
| Injection site nodule | 1 (<0.1) | 0 | 1 (<0.1) |
| Injection site paraesthesia | 1 (<0.1) | 0 | 1 (<0.1) |
| Malaise | 2 (<0.1) | 0 | 2 (<0.1) |
| Peripheral swelling | 1 (<0.1) | 0 | 1 (<0.1) |
| Swelling | 1 (<0.1) | 0 | 1 (<0.1) |
| Investigations | 2 (<0.1) | 5 (0.1) | 7 (<0.1) |
| Blood pressure increased | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |

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Table 14.3.1.11.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days
After Any Injection
Safety Set

Age Group: >=65 Years

| System Organ Class Preferred Term | Placebo (N=3750) n (%) | mRNA-1273 (N=3770) n (%) | Total (N=7520) n (%) |
|--|------------------------------|--------------------------------|----------------------------|
| Investigations (Cont.) | | | |
| Blood pressure diastolic increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Blood pressure systolic increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Heart rate increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Blood glucose increased | 1 (<0.1) | 0 | 1 (<0.1) |
| Injury, poisoning and procedural complications | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Tooth fracture | 0 | 1 (<0.1) | 1 (<0.1) |
| Fall | 1 (<0.1) | 0 | 1 (<0.1) |
| Ulnar nerve injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Uncoded | 3 (<0.1) | 27 (0.7) | 30 (0.4) |
| Uncoded | 3 (<0.1) | 27 (0.7) | 30 (0.4) |

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Table 14.3.1.13.3
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Number of Subjects Reporting Unsolicited Adverse Events | 120 (0.8) | 113 (0.7) | 233 (0.8) |
| Number of Unsolicited Adverse Events | 164 | 148 | 312 |
| Infections and infestations | 21 (0.1) | 15 (<0.1) | 36 (0.1) |
| Pneumonia | 5 (<0.1) | 3 (<0.1) | 8 (<0.1) |
| Appendicitis | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Bronchitis | 0 | 1 (<0.1) | 1 (<0.1) |
| COVID-19 | 6 (<0.1) | 1 (<0.1) | 7 (<0.1) |
| Cellulitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Clostridium difficile infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Hepatitis A | 0 | 1 (<0.1) | 1 (<0.1) |
| Pneumonia staphylococcal | 0 | 1 (<0.1) | 1 (<0.1) |
| Postoperative abscess | 0 | 1 (<0.1) | 1 (<0.1) |
| Postoperative wound infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Sepsis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Toxic shock syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Diverticulitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Osteomyelitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Pharyngitis streptococcal | 1 (<0.1) | 0 | 1 (<0.1) |
| Pyelonephritis acute | 1 (<0.1) | 0 | 1 (<0.1) |
| Septic shock | 1 (<0.1) | 0 | 1 (<0.1) |
| Streptococcal sepsis | 1 (<0.1) | 0 | 1 (<0.1) |
| Urinary tract infection | 3 (<0.1) | 0 | 3 (<0.1) |

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Table 14.3.1.13.3
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 6 (<0.1) | 9 (<0.1) | 15 (<0.1) |
| Prostate cancer | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| B-cell small lymphocytic lymphoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Chronic lymphocytic leukaemia | 0 | 1 (<0.1) | 1 (<0.1) |
| Gastric cancer | 0 | 1 (<0.1) | 1 (<0.1) |
| Lung cancer metastatic | 0 | 1 (<0.1) | 1 (<0.1) |
| Malignant melanoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Oesophageal carcinoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Pelvic neoplasm | 0 | 1 (<0.1) | 1 (<0.1) |
| Breast cancer stage I | 1 (<0.1) | 0 | 1 (<0.1) |
| Colon cancer stage III | 1 (<0.1) | 0 | 1 (<0.1) |
| Intraductal proliferative breast lesion | 1 (<0.1) | 0 | 1 (<0.1) |
| Blood and lymphatic system disorders | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Blood loss anaemia | 0 | 1 (<0.1) | 1 (<0.1) |
| Anaemia | 1 (<0.1) | 0 | 1 (<0.1) |
| Metabolism and nutrition disorders | 5 (<0.1) | 3 (<0.1) | 8 (<0.1) |
| Dehydration | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Diabetic ketoacidosis | 0 | 1 (<0.1) | 1 (<0.1) |
| Gout | 1 (<0.1) | 0 | 1 (<0.1) |
| Hypomagnesaemia | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.13.3
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Psychiatric disorders | 8 (<0.1) | 4 (<0.1) | 12 (<0.1) |
| Alcohol abuse | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Alcohol withdrawal syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Completed suicide | 0 | 1 (<0.1) | 1 (<0.1) |
| Intentional self-injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Schizoaffective disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Anxiety | 1 (<0.1) | 0 | 1 (<0.1) |
| Anxiety disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Confusional state | 2 (<0.1) | 0 | 2 (<0.1) |
| Depression | 2 (<0.1) | 0 | 2 (<0.1) |
| Major depression | 1 (<0.1) | 0 | 1 (<0.1) |
| Psychotic disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Nervous system disorders | 9 (<0.1) | 11 (<0.1) | 20 (<0.1) |
| Cerebrovascular accident | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Embolic stroke | 0 | 2 (<0.1) | 2 (<0.1) |
| Seizure | 0 | 2 (<0.1) | 2 (<0.1) |
| Syncope | 4 (<0.1) | 2 (<0.1) | 6 (<0.1) |
| Facial paralysis | 0 | 1 (<0.1) | 1 (<0.1) |
| Toxic encephalopathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Transient ischaemic attack | 0 | 1 (<0.1) | 1 (<0.1) |
| Basal ganglia haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Ischaemic stroke | 1 (<0.1) | 0 | 1 (<0.1) |
| Migraine | 1 (<0.1) | 0 | 1 (<0.1) |
| Paraesthesia | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.13.3
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Nervous system disorders (Cont.) | | | |
| Speech disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Eye disorders | 1 (<0.1) | 0 | 1 (<0.1) |
| Retinal detachment | 1 (<0.1) | 0 | 1 (<0.1) |
| Retinal tear | 1 (<0.1) | 0 | 1 (<0.1) |
| Cardiac disorders | 19 (0.1) | 16 (0.1) | 35 (0.1) |
| Myocardial infarction | 3 (<0.1) | 5 (<0.1) | 8 (<0.1) |
| Atrial fibrillation | 4 (<0.1) | 3 (<0.1) | 7 (<0.1) |
| Coronary artery disease | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Cardiac failure congestive | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Acute coronary syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Acute myocardial infarction | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Cardio-respiratory arrest | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Chronic left ventricular failure | 0 | 1 (<0.1) | 1 (<0.1) |
| Acute left ventricular failure | 1 (<0.1) | 0 | 1 (<0.1) |
| Atrial flutter | 1 (<0.1) | 0 | 1 (<0.1) |
| Bradycardia | 1 (<0.1) | 0 | 1 (<0.1) |
| Cardiac failure | 1 (<0.1) | 0 | 1 (<0.1) |
| Cardiac failure acute | 1 (<0.1) | 0 | 1 (<0.1) |
| Pericarditis | 1 (<0.1) | 0 | 1 (<0.1) |
| Tachycardia | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.13.3
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Vascular disorders | 9 (<0.1) | 5 (<0.1) | 14 (<0.1) |
| Hypertension | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Deep vein thrombosis | 0 | 1 (<0.1) | 1 (<0.1) |
| Hypertensive urgency | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Hypotension | 0 | 1 (<0.1) | 1 (<0.1) |
| Accelerated hypertension | 1 (<0.1) | 0 | 1 (<0.1) |
| Aortic aneurysm | 1 (<0.1) | 0 | 1 (<0.1) |
| Aortic stenosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Fibromuscular dysplasia | 1 (<0.1) | 0 | 1 (<0.1) |
| Hypertensive emergency | 2 (<0.1) | 0 | 2 (<0.1) |
| Peripheral artery aneurysm | 1 (<0.1) | 0 | 1 (<0.1) |
| Respiratory, thoracic and mediastinal disorders | 15 (<0.1) | 7 (<0.1) | 22 (<0.1) |
| Pulmonary embolism | 4 (<0.1) | 3 (<0.1) | 7 (<0.1) |
| Acute respiratory failure | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Atelectasis | 0 | 1 (<0.1) | 1 (<0.1) |
| Dyspnoea | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Emphysema | 0 | 1 (<0.1) | 1 (<0.1) |
| Chronic obstructive pulmonary disease | 2 (<0.1) | 0 | 2 (<0.1) |
| Hypoxia | 1 (<0.1) | 0 | 1 (<0.1) |
| Laryngeal oedema | 1 (<0.1) | 0 | 1 (<0.1) |
| Organising pneumonia | 1 (<0.1) | 0 | 1 (<0.1) |
| Pleural effusion | 1 (<0.1) | 0 | 1 (<0.1) |
| Pleuritic pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Pneumonia aspiration | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.13.3
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Respiratory, thoracic and mediastinal disorders (Cont.) | | | |
| Respiratory failure | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastrointestinal disorders | 7 (<0.1) | 14 (<0.1) | 21 (<0.1) |
| Colitis | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Nausea | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Abdominal pain upper | 0 | 1 (<0.1) | 1 (<0.1) |
| Diarrhoea | 0 | 1 (<0.1) | 1 (<0.1) |
| Diverticular perforation | 0 | 1 (<0.1) | 1 (<0.1) |
| Duodenal ulcer | 0 | 1 (<0.1) | 1 (<0.1) |
| Gastrooesophageal reflux disease | 0 | 1 (<0.1) | 1 (<0.1) |
| Hiatus hernia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Large intestine perforation | 0 | 1 (<0.1) | 1 (<0.1) |
| Pancreatitis acute | 0 | 1 (<0.1) | 1 (<0.1) |
| Small intestinal obstruction | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Volvulus | 0 | 1 (<0.1) | 1 (<0.1) |
| Vomiting | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Abdominal pain | 2 (<0.1) | 0 | 2 (<0.1) |
| Duodenal ulcer haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Food poisoning | 1 (<0.1) | 0 | 1 (<0.1) |
| Hepatobiliary disorders | 0 | 3 (<0.1) | 3 (<0.1) |
| Bile duct stone | 0 | 1 (<0.1) | 1 (<0.1) |
| Cholecystitis | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.13.3
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Hepatobiliary disorders (Cont.) | | | |
| Hepatic mass | 0 | 1 (<0.1) | 1 (<0.1) |
| Skin and subcutaneous tissue disorders | 2 (<0.1) | 0 | 2 (<0.1) |
| Angioedema | 1 (<0.1) | 0 | 1 (<0.1) |
| Dermatitis bullous | 1 (<0.1) | 0 | 1 (<0.1) |
| Musculoskeletal and connective tissue disorders | 7 (<0.1) | 11 (<0.1) | 18 (<0.1) |
| Arthritis | 0 | 1 (<0.1) | 1 (<0.1) |
| Back pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Fracture nonunion | 0 | 1 (<0.1) | 1 (<0.1) |
| Intervertebral disc degeneration | 0 | 1 (<0.1) | 1 (<0.1) |
| Intervertebral disc protrusion | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Muscle spasms | 0 | 1 (<0.1) | 1 (<0.1) |
| Musculoskeletal chest pain | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Neck pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Osteoarthritis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Rheumatoid arthritis | 0 | 1 (<0.1) | 1 (<0.1) |
| Spinal stenosis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Arthralgia | 1 (<0.1) | 0 | 1 (<0.1) |
| Polymyalgia rheumatica | 1 (<0.1) | 0 | 1 (<0.1) |
| Renal and urinary disorders | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |
| Nephrolithiasis | 0 | 4 (<0.1) | 4 (<0.1) |
| Acute kidney injury | 2 (<0.1) | 0 | 2 (<0.1) |

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Table 14.3.1.13.3
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Renal and urinary disorders (Cont.) | | | |
| Chronic kidney disease | 1 (<0.1) | 0 | 1 (<0.1) |
| Pregnancy, puerperium and perinatal conditions | 1 (<0.1) | 0 | 1 (<0.1) |
| Abortion spontaneous | 1 (<0.1) | 0 | 1 (<0.1) |
| Reproductive system and breast disorders | 0 | 2 (<0.1) | 2 (<0.1) |
| Ovarian cyst | 0 | 1 (<0.1) | 1 (<0.1) |
| Uterine haemorrhage | 0 | 1 (<0.1) | 1 (<0.1) |
| General disorders and administration site conditions | 6 (<0.1) | 5 (<0.1) | 11 (<0.1) |
| Swelling face | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Chest pain | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Non-cardiac chest pain | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Oedema peripheral | 0 | 1 (<0.1) | 1 (<0.1) |
| Feeling hot | 1 (<0.1) | 0 | 1 (<0.1) |
| Incarcerated hernia | 1 (<0.1) | 0 | 1 (<0.1) |
| Precancerous condition | 1 (<0.1) | 0 | 1 (<0.1) |
| Injury, poisoning and procedural complications | 12 (<0.1) | 11 (<0.1) | 23 (<0.1) |
| Cervical vertebral fracture | 0 | 2 (<0.1) | 2 (<0.1) |
| Road traffic accident | 0 | 2 (<0.1) | 2 (<0.1) |
| Back injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Concussion | 0 | 1 (<0.1) | 1 (<0.1) |

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.13.3
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Injury, poisoning and procedural complications (Cont.) | | | |
| Craniocerebral injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Facial bones fracture | 0 | 1 (<0.1) | 1 (<0.1) |
| Fall | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Femoral neck fracture | 0 | 1 (<0.1) | 1 (<0.1) |
| Femur fracture | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Head injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Hip fracture | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Overdose | 0 | 1 (<0.1) | 1 (<0.1) |
| Skin laceration | 0 | 1 (<0.1) | 1 (<0.1) |
| Subdural haematoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Tendon rupture | 0 | 1 (<0.1) | 1 (<0.1) |
| Traumatic liver injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Abdominal injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Ankle fracture | 1 (<0.1) | 0 | 1 (<0.1) |
| Fracture | 1 (<0.1) | 0 | 1 (<0.1) |
| Immunisation anxiety related reaction | 1 (<0.1) | 0 | 1 (<0.1) |
| Joint injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Post procedural haematoma | 1 (<0.1) | 0 | 1 (<0.1) |
| Post procedural haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Rib fracture | 1 (<0.1) | 0 | 1 (<0.1) |
| Surgical and medical procedures | 3 (<0.1) | 5 (<0.1) | 8 (<0.1) |
| Thyroidectomy | 0 | 2 (<0.1) | 2 (<0.1) |

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.13.3
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Surgical and medical procedures (Cont.) | | | |
| Ankle arthroplasty | 0 | 1 (<0.1) | 1 (<0.1) |
| Spinal fusion surgery | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Transurethral prostatectomy | 0 | 1 (<0.1) | 1 (<0.1) |
| Hip arthroplasty | 1 (<0.1) | 0 | 1 (<0.1) |
| Umbilical hernia repair | 1 (<0.1) | 0 | 1 (<0.1) |
| Social circumstances | 1 (<0.1) | 0 | 1 (<0.1) |
| Sexual abuse | 1 (<0.1) | 0 | 1 (<0.1) |
| Product issues | 1 (<0.1) | 0 | 1 (<0.1) |
| Lead dislodgement | 1 (<0.1) | 0 | 1 (<0.1) |
| Uncoded | 11 (<0.1) | 8 (<0.1) | 19 (<0.1) |
| Uncoded | 11 (<0.1) | 8 (<0.1) | 19 (<0.1) |

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.14.1
Subject Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Number of Subjects Reporting Unsolicited Adverse Events | 4 (<0.1) | 5 (<0.1) | 9 (<0.1) |
| Number of Unsolicited Adverse Events | 8 | 7 | 15 |
| Nervous system disorders | 1 (<0.1) | 0 | 1 (<0.1) |
| Paraesthesia | 1 (<0.1) | 0 | 1 (<0.1) |
| Respiratory, thoracic and mediastinal disorders | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Dyspnoea | 0 | 1 (<0.1) | 1 (<0.1) |
| Pulmonary embolism | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastrointestinal disorders | 0 | 1 (<0.1) | 1 (<0.1) |
| Nausea | 0 | 1 (<0.1) | 1 (<0.1) |
| Vomiting | 0 | 1 (<0.1) | 1 (<0.1) |
| Musculoskeletal and connective tissue disorders | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Rheumatoid arthritis | 0 | 1 (<0.1) | 1 (<0.1) |
| Polymyalgia rheumatica | 1 (<0.1) | 0 | 1 (<0.1) |
| General disorders and administration site conditions | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Swelling face | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Oedema peripheral | 0 | 1 (<0.1) | 1 (<0.1) |
| Feeling hot | 1 (<0.1) | 0 | 1 (<0.1) |

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.14.1
Subject Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Injury, poisoning and procedural complications | 1 (<0.1) | 0 | 1 (<0.1) |
| Immunisation anxiety related reaction | 1 (<0.1) | 0 | 1 (<0.1) |
| Uncoded | 1 (<0.1) | 0 | 1 (<0.1) |
| Uncoded | 1 (<0.1) | 0 | 1 (<0.1) |

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.14.3
Subject Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Number of Subjects Reporting Unsolicited Adverse Events | 5 (<0.1) | 6 (<0.1) | 11 (<0.1) |
| Number of Unsolicited Adverse Events | 14 | 8 | 22 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 1 (<0.1) | 1 (<0.1) |
| B-cell small lymphocytic lymphoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Metabolism and nutrition disorders | 1 (<0.1) | 0 | 1 (<0.1) |
| Hypomagnesaemia | 1 (<0.1) | 0 | 1 (<0.1) |
| Nervous system disorders | 1 (<0.1) | 0 | 1 (<0.1) |
| Paraesthesia | 1 (<0.1) | 0 | 1 (<0.1) |
| Cardiac disorders | 1 (<0.1) | 0 | 1 (<0.1) |
| Acute myocardial infarction | 1 (<0.1) | 0 | 1 (<0.1) |
| Atrial fibrillation | 1 (<0.1) | 0 | 1 (<0.1) |
| Respiratory, thoracic and mediastinal disorders | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Dyspnoea | 0 | 1 (<0.1) | 1 (<0.1) |
| Organising pneumonia | 1 (<0.1) | 0 | 1 (<0.1) |
| Pulmonary embolism | 1 (<0.1) | 0 | 1 (<0.1) |
| Respiratory failure | 1 (<0.1) | 0 | 1 (<0.1) |

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.14.3
Subject Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Gastrointestinal disorders | 0 | 1 (<0.1) | 1 (<0.1) |
| Nausea | 0 | 1 (<0.1) | 1 (<0.1) |
| Vomiting | 0 | 1 (<0.1) | 1 (<0.1) |
| Musculoskeletal and connective tissue disorders | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Rheumatoid arthritis | 0 | 1 (<0.1) | 1 (<0.1) |
| Polymyalgia rheumatica | 1 (<0.1) | 0 | 1 (<0.1) |
| Renal and urinary disorders | 1 (<0.1) | 0 | 1 (<0.1) |
| Acute kidney injury | 1 (<0.1) | 0 | 1 (<0.1) |
| General disorders and administration site conditions | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Swelling face | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Oedema peripheral | 0 | 1 (<0.1) | 1 (<0.1) |
| Feeling hot | 1 (<0.1) | 0 | 1 (<0.1) |
| Injury, poisoning and procedural complications | 1 (<0.1) | 0 | 1 (<0.1) |
| Immunisation anxiety related reaction | 1 (<0.1) | 0 | 1 (<0.1) |
| Uncoded | 1 (<0.1) | 0 | 1 (<0.1) |
| Uncoded | 1 (<0.1) | 0 | 1 (<0.1) |

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.15.1

Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Number of Subjects Reporting Unsolicited Adverse Events | 85 (0.6) | 45 (0.3) | 130 (0.4) |
| Number of Unsolicited Adverse Events | 98 | 58 | 156 |
| Infections and infestations | 44 (0.3) | 15 (<0.1) | 59 (0.2) |
| COVID-19 | 38 (0.3) | 10 (<0.1) | 48 (0.2) |
| Asymptomatic COVID-19 | 0 | 1 (<0.1) | 1 (<0.1) |
| Ear infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Hepatitis A | 0 | 1 (<0.1) | 1 (<0.1) |
| Pneumonia | 0 | 1 (<0.1) | 1 (<0.1) |
| Sepsis | 0 | 1 (<0.1) | 1 (<0.1) |
| Diverticulitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Osteomyelitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Pyelonephritis acute | 1 (<0.1) | 0 | 1 (<0.1) |
| Upper respiratory tract infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Urinary tract infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Varicella zoster virus infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Benign hepatic neoplasm | 0 | 1 (<0.1) | 1 (<0.1) |
| Gastric cancer | 0 | 1 (<0.1) | 1 (<0.1) |
| Lung cancer metastatic | 0 | 1 (<0.1) | 1 (<0.1) |
| Colon cancer stage III | 1 (<0.1) | 0 | 1 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.15.1

Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.) | | | |
| Prostate cancer | 1 (<0.1) | 0 | 1 (<0.1) |
| Blood and lymphatic system disorders | 0 | 1 (<0.1) | 1 (<0.1) |
| Lymphadenopathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Immune system disorders | 0 | 1 (<0.1) | 1 (<0.1) |
| Seasonal allergy | 0 | 1 (<0.1) | 1 (<0.1) |
| Metabolism and nutrition disorders | 3 (<0.1) | 0 | 3 (<0.1) |
| Dehydration | 1 (<0.1) | 0 | 1 (<0.1) |
| Hyperglycaemia | 1 (<0.1) | 0 | 1 (<0.1) |
| Hypomagnesaemia | 1 (<0.1) | 0 | 1 (<0.1) |
| Psychiatric disorders | 4 (<0.1) | 1 (<0.1) | 5 (<0.1) |
| Substance abuse | 0 | 1 (<0.1) | 1 (<0.1) |
| Anxiety | 1 (<0.1) | 0 | 1 (<0.1) |
| Confusional state | 1 (<0.1) | 0 | 1 (<0.1) |
| Depression | 1 (<0.1) | 0 | 1 (<0.1) |
| Depression suicidal | 1 (<0.1) | 0 | 1 (<0.1) |
| Nervous system disorders | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Cervical radiculopathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Headache | 0 | 1 (<0.1) | 1 (<0.1) |

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.15.1

Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Nervous system disorders (Cont.) | | | |
| Idiopathic intracranial hypertension | 0 | 1 (<0.1) | 1 (<0.1) |
| Ischaemic stroke | 1 (<0.1) | 0 | 1 (<0.1) |
| Migraine | 1 (<0.1) | 0 | 1 (<0.1) |
| Speech disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Eye disorders | 2 (<0.1) | 0 | 2 (<0.1) |
| Eye swelling | 1 (<0.1) | 0 | 1 (<0.1) |
| Retinal detachment | 1 (<0.1) | 0 | 1 (<0.1) |
| Ear and labyrinth disorders | 1 (<0.1) | 0 | 1 (<0.1) |
| Vertigo | 1 (<0.1) | 0 | 1 (<0.1) |
| Cardiac disorders | 6 (<0.1) | 2 (<0.1) | 8 (<0.1) |
| Cardiac failure congestive | 0 | 1 (<0.1) | 1 (<0.1) |
| Coronary artery disease | 0 | 1 (<0.1) | 1 (<0.1) |
| Acute myocardial infarction | 2 (<0.1) | 0 | 2 (<0.1) |
| Arrhythmia | 2 (<0.1) | 0 | 2 (<0.1) |
| Atrial fibrillation | 1 (<0.1) | 0 | 1 (<0.1) |
| Palpitations | 1 (<0.1) | 0 | 1 (<0.1) |
| Vascular disorders | 2 (<0.1) | 0 | 2 (<0.1) |
| Deep vein thrombosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Hypertension | 1 (<0.1) | 0 | 1 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.15.1

Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Respiratory, thoracic and mediastinal disorders | 5 (<0.1) | 0 | 5 (<0.1) |
| Acute respiratory failure | 1 (<0.1) | 0 | 1 (<0.1) |
| Dyspnoea | 1 (<0.1) | 0 | 1 (<0.1) |
| Pleurisy | 1 (<0.1) | 0 | 1 (<0.1) |
| Pulmonary embolism | 1 (<0.1) | 0 | 1 (<0.1) |
| Respiratory failure | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastrointestinal disorders | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Lip swelling | 0 | 1 (<0.1) | 1 (<0.1) |
| Pancreatitis acute | 0 | 1 (<0.1) | 1 (<0.1) |
| Swollen tongue | 0 | 1 (<0.1) | 1 (<0.1) |
| Nausea | 1 (<0.1) | 0 | 1 (<0.1) |
| Retching | 1 (<0.1) | 0 | 1 (<0.1) |
| Hepatobiliary disorders | 0 | 1 (<0.1) | 1 (<0.1) |
| Bile duct stone | 0 | 1 (<0.1) | 1 (<0.1) |
| Skin and subcutaneous tissue disorders | 3 (<0.1) | 5 (<0.1) | 8 (<0.1) |
| Urticaria | 0 | 3 (<0.1) | 3 (<0.1) |
| Psoriasis | 0 | 1 (<0.1) | 1 (<0.1) |
| Rash | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Angioedema | 1 (<0.1) | 0 | 1 (<0.1) |
| Rash pruritic | 1 (<0.1) | 0 | 1 (<0.1) |

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.15.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Musculoskeletal and connective tissue disorders | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Arthralgia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Arthritis | 0 | 1 (<0.1) | 1 (<0.1) |
| Fracture nonunion | 0 | 1 (<0.1) | 1 (<0.1) |
| Pain in extremity | 0 | 1 (<0.1) | 1 (<0.1) |
| Rheumatoid arthritis | 0 | 1 (<0.1) | 1 (<0.1) |
| Polymyalgia rheumatica | 1 (<0.1) | 0 | 1 (<0.1) |
| Renal and urinary disorders | 1 (<0.1) | 0 | 1 (<0.1) |
| Acute kidney injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Pregnancy, puerperium and perinatal conditions | 0 | 1 (<0.1) | 1 (<0.1) |
| Morning sickness | 0 | 1 (<0.1) | 1 (<0.1) |
| Reproductive system and breast disorders | 0 | 1 (<0.1) | 1 (<0.1) |
| Breast mass | 0 | 1 (<0.1) | 1 (<0.1) |
| General disorders and administration site conditions | 7 (<0.1) | 5 (<0.1) | 12 (<0.1) |
| Injection site erythema | 0 | 3 (<0.1) | 3 (<0.1) |
| Induration | 0 | 1 (<0.1) | 1 (<0.1) |
| Influenza like illness | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Chest pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Fatigue | 1 (<0.1) | 0 | 1 (<0.1) |
| Incarcerated hernia | 1 (<0.1) | 0 | 1 (<0.1) |

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.15.1

Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| General disorders and administration site conditions (Cont.) | | | |
| Non-cardiac chest pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Pyrexia | 1 (<0.1) | 0 | 1 (<0.1) |
| Investigations | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Hepatic enzyme increased | 0 | 1 (<0.1) | 1 (<0.1) |
| SARS-CoV-2 test positive | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Blood pressure diastolic increased | 1 (<0.1) | 0 | 1 (<0.1) |
| Injury, poisoning and procedural complications | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |
| Head injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Hip fracture | 0 | 1 (<0.1) | 1 (<0.1) |
| Overdose | 0 | 1 (<0.1) | 1 (<0.1) |
| Road traffic accident | 0 | 1 (<0.1) | 1 (<0.1) |
| Abdominal injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Procedural anxiety | 1 (<0.1) | 0 | 1 (<0.1) |
| Ulnar nerve injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Uncoded | 4 (<0.1) | 4 (<0.1) | 8 (<0.1) |
| Uncoded | 4 (<0.1) | 4 (<0.1) | 8 (<0.1) |

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.17.1
Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Number of Subjects Reporting Unsolicited Adverse Events | 190 (1.3) | 216 (1.4) | 406 (1.3) |
| Number of Unsolicited Adverse Events | 225 | 275 | 500 |
| Infections and infestations | 25 (0.2) | 13 (<0.1) | 38 (0.1) |
| Pneumonia | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Appendicitis | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Clostridium difficile infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Conjunctivitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Ear infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Hepatitis A | 0 | 1 (<0.1) | 1 (<0.1) |
| Pharyngitis streptococcal | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Proctitis chlamydial | 0 | 1 (<0.1) | 1 (<0.1) |
| Sinusitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Tooth infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Toxic shock syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Urinary tract infection | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Bacterial vaginosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Bronchitis | 2 (<0.1) | 0 | 2 (<0.1) |
| COVID-19 | 2 (<0.1) | 0 | 2 (<0.1) |
| Cellulitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Diverticulitis | 3 (<0.1) | 0 | 3 (<0.1) |
| Fungal infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Genital herpes | 1 (<0.1) | 0 | 1 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.17.1

Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Infections and infestations (Cont.) | | | |
| Gingivitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Osteomyelitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Streptococcal sepsis | 1 (<0.1) | 0 | 1 (<0.1) |
| Tooth abscess | 1 (<0.1) | 0 | 1 (<0.1) |
| Upper respiratory tract infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Viral infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 5 (<0.1) | 7 (<0.1) | 12 (<0.1) |
| Prostate cancer | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Basal cell carcinoma | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Lung cancer metastatic | 0 | 1 (<0.1) | 1 (<0.1) |
| Malignant melanoma in situ | 0 | 1 (<0.1) | 1 (<0.1) |
| Rectal cancer | 0 | 1 (<0.1) | 1 (<0.1) |
| Thyroid cancer | 0 | 1 (<0.1) | 1 (<0.1) |
| Breast cancer | 1 (<0.1) | 0 | 1 (<0.1) |
| Malignant melanoma | 1 (<0.1) | 0 | 1 (<0.1) |
| Squamous cell carcinoma | 1 (<0.1) | 0 | 1 (<0.1) |
| Blood and lymphatic system disorders | 0 | 2 (<0.1) | 2 (<0.1) |
| Lymphadenopathy | 0 | 2 (<0.1) | 2 (<0.1) |
| Immune system disorders | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Seasonal allergy | 0 | 1 (<0.1) | 1 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.17.1

Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Immune system disorders (Cont.) | | | |
| Type IV hypersensitivity reaction | 0 | 1 (<0.1) | 1 (<0.1) |
| Anaphylactic reaction | 1 (<0.1) | 0 | 1 (<0.1) |
| Metabolism and nutrition disorders | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Decreased appetite | 0 | 1 (<0.1) | 1 (<0.1) |
| Diabetes mellitus inadequate control | 0 | 1 (<0.1) | 1 (<0.1) |
| Dehydration | 1 (<0.1) | 0 | 1 (<0.1) |
| Hypokalaemia | 1 (<0.1) | 0 | 1 (<0.1) |
| Psychiatric disorders | 7 (<0.1) | 3 (<0.1) | 10 (<0.1) |
| Depression | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Insomnia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Schizoaffective disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Anxiety | 3 (<0.1) | 0 | 3 (<0.1) |
| Confusional state | 1 (<0.1) | 0 | 1 (<0.1) |
| Major depression | 1 (<0.1) | 0 | 1 (<0.1) |
| Psychotic disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Nervous system disorders | 21 (0.1) | 27 (0.2) | 48 (0.2) |
| Headache | 13 (<0.1) | 19 (0.1) | 32 (0.1) |
| Dizziness | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Syncope | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Cerebrovascular accident | 0 | 1 (<0.1) | 1 (<0.1) |
| Migraine | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.17.1

Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Nervous system disorders (Cont.) | | | |
| Movement disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Sciatica | 0 | 1 (<0.1) | 1 (<0.1) |
| Ischaemic stroke | 1 (<0.1) | 0 | 1 (<0.1) |
| Presyncope | 1 (<0.1) | 0 | 1 (<0.1) |
| Seizure | 1 (<0.1) | 0 | 1 (<0.1) |
| Eye disorders | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Ocular hyperaemia | 0 | 1 (<0.1) | 1 (<0.1) |
| Retinal detachment | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Ear and labyrinth disorders | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Vertigo | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Cardiac disorders | 13 (<0.1) | 11 (<0.1) | 24 (<0.1) |
| Atrial fibrillation | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Bradycardia | 5 (<0.1) | 3 (<0.1) | 8 (<0.1) |
| Coronary artery disease | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Cardiomyopathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Myocardial infarction | 0 | 1 (<0.1) | 1 (<0.1) |
| Acute left ventricular failure | 1 (<0.1) | 0 | 1 (<0.1) |
| Cardiac failure acute | 1 (<0.1) | 0 | 1 (<0.1) |
| Tachycardia | 3 (<0.1) | 0 | 3 (<0.1) |
| Ventricular fibrillation | 1 (<0.1) | 0 | 1 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.17.1

Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Vascular disorders | 39 (0.3) | 28 (0.2) | 67 (0.2) |
| Hypertension | 29 (0.2) | 22 (0.1) | 51 (0.2) |
| Systolic hypertension | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Aortic aneurysm | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Hypertensive urgency | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Peripheral artery occlusion | 0 | 1 (<0.1) | 1 (<0.1) |
| Accelerated hypertension | 1 (<0.1) | 0 | 1 (<0.1) |
| Deep vein thrombosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Hypertensive emergency | 1 (<0.1) | 0 | 1 (<0.1) |
| Hypotension | 1 (<0.1) | 0 | 1 (<0.1) |
| Phlebitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Respiratory, thoracic and mediastinal disorders | 9 (<0.1) | 8 (<0.1) | 17 (<0.1) |
| Dyspnoea | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Asthma | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Cough | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Nasal congestion | 0 | 1 (<0.1) | 1 (<0.1) |
| Oropharyngeal pain | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Pleurisy | 0 | 1 (<0.1) | 1 (<0.1) |
| Pulmonary embolism | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Rhinorrhoea | 0 | 1 (<0.1) | 1 (<0.1) |
| Chronic obstructive pulmonary disease | 2 (<0.1) | 0 | 2 (<0.1) |
| Respiratory tract congestion | 1 (<0.1) | 0 | 1 (<0.1) |
| Wheezing | 1 (<0.1) | 0 | 1 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.17.1

Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Gastrointestinal disorders | 14 (<0.1) | 16 (0.1) | 30 (<0.1) |
| Nausea | 1 (<0.1) | 4 (<0.1) | 5 (<0.1) |
| Colitis | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Abdominal pain | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Diarrhoea | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Abdominal pain upper | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Diverticulum | 0 | 1 (<0.1) | 1 (<0.1) |
| Duodenal ulcer | 0 | 1 (<0.1) | 1 (<0.1) |
| Enteritis | 0 | 1 (<0.1) | 1 (<0.1) |
| Large intestine perforation | 0 | 1 (<0.1) | 1 (<0.1) |
| Pancreatitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Small intestinal obstruction | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Umbilical hernia | 0 | 1 (<0.1) | 1 (<0.1) |
| Volvulus | 0 | 1 (<0.1) | 1 (<0.1) |
| Abdominal discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Duodenal ulcer haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Femoral hernia | 1 (<0.1) | 0 | 1 (<0.1) |
| Food poisoning | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastrointestinal haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Retching | 1 (<0.1) | 0 | 1 (<0.1) |
| Hepatobiliary disorders | 0 | 2 (<0.1) | 2 (<0.1) |
| Cholelithiasis | 0 | 2 (<0.1) | 2 (<0.1) |

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Table 14.3.1.17.1

Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Skin and subcutaneous tissue disorders | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Rash | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Dermatitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Erythema | 0 | 1 (<0.1) | 1 (<0.1) |
| Pruritus | 0 | 1 (<0.1) | 1 (<0.1) |
| Angioedema | 1 (<0.1) | 0 | 1 (<0.1) |
| Musculoskeletal and connective tissue disorders | 18 (0.1) | 24 (0.2) | 42 (0.1) |
| Myalgia | 0 | 11 (<0.1) | 11 (<0.1) |
| Arthralgia | 2 (<0.1) | 10 (<0.1) | 12 (<0.1) |
| Muscle spasms | 0 | 2 (<0.1) | 2 (<0.1) |
| Neck pain | 0 | 2 (<0.1) | 2 (<0.1) |
| Back pain | 5 (<0.1) | 1 (<0.1) | 6 (<0.1) |
| Pain in extremity | 0 | 1 (<0.1) | 1 (<0.1) |
| Spinal stenosis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Temporomandibular joint syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Tendonitis | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Arthritis | 1 (<0.1) | 0 | 1 (<0.1) |
| Costochondritis | 1 (<0.1) | 0 | 1 (<0.1) |
| Joint swelling | 1 (<0.1) | 0 | 1 (<0.1) |
| Musculoskeletal chest pain | 2 (<0.1) | 0 | 2 (<0.1) |
| Osteoarthritis | 1 (<0.1) | 0 | 1 (<0.1) |
| Polymyalgia rheumatica | 1 (<0.1) | 0 | 1 (<0.1) |
| Rotator cuff syndrome | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.17.1

Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Renal and urinary disorders | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Nephrolithiasis | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Acute kidney injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Renal colic | 1 (<0.1) | 0 | 1 (<0.1) |
| Reproductive system and breast disorders | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Breast mass | 0 | 1 (<0.1) | 1 (<0.1) |
| Uterine haemorrhage | 0 | 1 (<0.1) | 1 (<0.1) |
| Dysmenorrhoea | 1 (<0.1) | 0 | 1 (<0.1) |
| General disorders and administration site conditions | 13 (<0.1) | 43 (0.3) | 56 (0.2) |
| Fatigue | 7 (<0.1) | 12 (<0.1) | 19 (<0.1) |
| Injection site erythema | 0 | 11 (<0.1) | 11 (<0.1) |
| Injection site pain | 1 (<0.1) | 6 (<0.1) | 7 (<0.1) |
| Injection site swelling | 0 | 4 (<0.1) | 4 (<0.1) |
| Chills | 0 | 2 (<0.1) | 2 (<0.1) |
| Pain | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Pyrexia | 0 | 2 (<0.1) | 2 (<0.1) |
| Adverse drug reaction | 0 | 1 (<0.1) | 1 (<0.1) |
| Chest discomfort | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site hypoaesthesia | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site induration | 0 | 1 (<0.1) | 1 (<0.1) |
| Malaise | 0 | 1 (<0.1) | 1 (<0.1) |
| Non-cardiac chest pain | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.17.1

Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| General disorders and administration site conditions (Cont.) | | | |
| Oedema peripheral | 0 | 1 (<0.1) | 1 (<0.1) |
| Swelling face | 0 | 1 (<0.1) | 1 (<0.1) |
| Asthenia | 1 (<0.1) | 0 | 1 (<0.1) |
| Chest pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Incarcerated hernia | 1 (<0.1) | 0 | 1 (<0.1) |
| Swelling | 1 (<0.1) | 0 | 1 (<0.1) |
| Investigations | 13 (<0.1) | 22 (0.1) | 35 (0.1) |
| Blood pressure increased | 7 (<0.1) | 10 (<0.1) | 17 (<0.1) |
| Blood pressure systolic increased | 6 (<0.1) | 8 (<0.1) | 14 (<0.1) |
| Blood pressure diastolic increased | 0 | 3 (<0.1) | 3 (<0.1) |
| Hepatic enzyme increased | 0 | 2 (<0.1) | 2 (<0.1) |
| Injury, poisoning and procedural complications | 13 (<0.1) | 16 (0.1) | 29 (<0.1) |
| Foot fracture | 0 | 3 (<0.1) | 3 (<0.1) |
| Skin laceration | 0 | 3 (<0.1) | 3 (<0.1) |
| Limb injury | 0 | 2 (<0.1) | 2 (<0.1) |
| Ankle fracture | 0 | 1 (<0.1) | 1 (<0.1) |
| Burns second degree | 0 | 1 (<0.1) | 1 (<0.1) |
| Cervical vertebral fracture | 0 | 1 (<0.1) | 1 (<0.1) |
| Facial bones fracture | 0 | 1 (<0.1) | 1 (<0.1) |
| Fall | 0 | 1 (<0.1) | 1 (<0.1) |
| Femoral neck fracture | 0 | 1 (<0.1) | 1 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.17.1

Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Injury, poisoning and procedural complications (Cont.) | | | |
| Fibula fracture | 0 | 1 (<0.1) | 1 (<0.1) |
| Head injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Hip fracture | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Ligament sprain | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Road traffic accident | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Subdural haematoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Tendon injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Tibia fracture | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Foreign body | 1 (<0.1) | 0 | 1 (<0.1) |
| Joint injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Lumbar vertebral fracture | 1 (<0.1) | 0 | 1 (<0.1) |
| Muscle rupture | 1 (<0.1) | 0 | 1 (<0.1) |
| Muscle strain | 2 (<0.1) | 0 | 2 (<0.1) |
| Post procedural haematoma | 1 (<0.1) | 0 | 1 (<0.1) |
| Post procedural haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Procedural haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Surgical and medical procedures | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Transurethral prostatectomy | 0 | 1 (<0.1) | 1 (<0.1) |
| Carpal tunnel decompression | 1 (<0.1) | 0 | 1 (<0.1) |
| Umbilical hernia repair | 1 (<0.1) | 0 | 1 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.17.1
Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Uncoded | 6 (<0.1) | 10 (<0.1) | 16 (<0.1) |
| Uncoded | 6 (<0.1) | 10 (<0.1) | 16 (<0.1) |

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

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Table 14.3.1.19.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Number of Subjects Reporting Unsolicited Adverse Events | 1276 (8.4) | 1215 (8.0) | 2491 (8.2) |
| Number of Unsolicited Adverse Events | 1837 | 1893 | 3730 |
| Infections and infestations | 437 (2.9) | 350 (2.3) | 787 (2.6) |
| Urinary tract infection | 72 (0.5) | 53 (0.3) | 125 (0.4) |
| Sinusitis | 21 (0.1) | 36 (0.2) | 57 (0.2) |
| Upper respiratory tract infection | 33 (0.2) | 24 (0.2) | 57 (0.2) |
| COVID-19 | 81 (0.5) | 14 (<0.1) | 95 (0.3) |
| Herpes zoster | 8 (<0.1) | 14 (<0.1) | 22 (<0.1) |
| Tooth infection | 8 (<0.1) | 14 (<0.1) | 22 (<0.1) |
| Tooth abscess | 17 (0.1) | 13 (<0.1) | 30 (<0.1) |
| Pharyngitis streptococcal | 15 (<0.1) | 11 (<0.1) | 26 (<0.1) |
| Cellulitis | 7 (<0.1) | 8 (<0.1) | 15 (<0.1) |
| Ear infection | 6 (<0.1) | 8 (<0.1) | 14 (<0.1) |
| Rhinovirus infection | 3 (<0.1) | 8 (<0.1) | 11 (<0.1) |
| Conjunctivitis | 4 (<0.1) | 7 (<0.1) | 11 (<0.1) |
| Gastroenteritis | 4 (<0.1) | 7 (<0.1) | 11 (<0.1) |
| Pharyngitis | 8 (<0.1) | 7 (<0.1) | 15 (<0.1) |
| Viral infection | 15 (<0.1) | 7 (<0.1) | 22 (<0.1) |
| Pneumonia | 8 (<0.1) | 6 (<0.1) | 14 (<0.1) |
| Diverticulitis | 7 (<0.1) | 5 (<0.1) | 12 (<0.1) |
| Localised infection | 7 (<0.1) | 5 (<0.1) | 12 (<0.1) |
| Paronychia | 2 (<0.1) | 5 (<0.1) | 7 (<0.1) |

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Table 14.3.1.19.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Infections and infestations (Cont.) | | | |
| Acute sinusitis | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |
| Gingivitis | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |
| Hordeolum | 4 (<0.1) | 4 (<0.1) | 8 (<0.1) |
| Otitis media | 4 (<0.1) | 4 (<0.1) | 8 (<0.1) |
| Abscess limb | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Bacterial vaginosis | 4 (<0.1) | 3 (<0.1) | 7 (<0.1) |
| Enterovirus infection | 0 | 3 (<0.1) | 3 (<0.1) |
| Folliculitis | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Fungal infection | 4 (<0.1) | 3 (<0.1) | 7 (<0.1) |
| Helicobacter infection | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Herpes simplex | 0 | 3 (<0.1) | 3 (<0.1) |
| Injection site cellulitis | 0 | 3 (<0.1) | 3 (<0.1) |
| Staphylococcal infection | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Subcutaneous abscess | 0 | 3 (<0.1) | 3 (<0.1) |
| Vulvovaginal candidiasis | 0 | 3 (<0.1) | 3 (<0.1) |
| Asymptomatic COVID-19 | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Bronchitis | 5 (<0.1) | 2 (<0.1) | 7 (<0.1) |
| Chlamydial infection | 0 | 2 (<0.1) | 2 (<0.1) |
| Chronic sinusitis | 0 | 2 (<0.1) | 2 (<0.1) |
| Clostridium difficile infection | 0 | 2 (<0.1) | 2 (<0.1) |
| Cystitis | 4 (<0.1) | 2 (<0.1) | 6 (<0.1) |
| Impetigo | 0 | 2 (<0.1) | 2 (<0.1) |
| Kidney infection | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Lyme disease | 0 | 2 (<0.1) | 2 (<0.1) |

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Table 14.3.1.19.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Infections and infestations (Cont.) | | | |
| Otitis externa | 8 (<0.1) | 2 (<0.1) | 10 (<0.1) |
| Otitis media acute | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Rhinitis | 4 (<0.1) | 2 (<0.1) | 6 (<0.1) |
| Skin infection | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Staphylococcal skin infection | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Tonsillitis | 5 (<0.1) | 2 (<0.1) | 7 (<0.1) |
| Upper respiratory tract infection bacterial | 0 | 2 (<0.1) | 2 (<0.1) |
| Viral upper respiratory tract infection | 6 (<0.1) | 2 (<0.1) | 8 (<0.1) |
| Appendicitis | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Body tinea | 0 | 1 (<0.1) | 1 (<0.1) |
| Candida infection | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Cat scratch disease | 0 | 1 (<0.1) | 1 (<0.1) |
| Catheter site infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Clostridium difficile colitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Dermatophytosis of nail | 0 | 1 (<0.1) | 1 (<0.1) |
| Furuncle | 0 | 1 (<0.1) | 1 (<0.1) |
| Hepatitis A | 0 | 1 (<0.1) | 1 (<0.1) |
| Infected bite | 0 | 1 (<0.1) | 1 (<0.1) |
| Infected cyst | 0 | 1 (<0.1) | 1 (<0.1) |
| Infected dermal cyst | 0 | 1 (<0.1) | 1 (<0.1) |
| Joint abscess | 0 | 1 (<0.1) | 1 (<0.1) |
| Large intestine infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Laryngitis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Laryngitis viral | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.19.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Infections and infestations (Cont.) | | | |
| Latent tuberculosis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Onychomycosis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Oral candidiasis | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Oral herpes | 0 | 1 (<0.1) | 1 (<0.1) |
| Osteomyelitis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Parainfluenzae virus infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Parotitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Periodontitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Pneumonia staphylococcal | 0 | 1 (<0.1) | 1 (<0.1) |
| Proctitis chlamydial | 0 | 1 (<0.1) | 1 (<0.1) |
| Respiratory tract infection | 4 (<0.1) | 1 (<0.1) | 5 (<0.1) |
| Respiratory tract infection viral | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Rocky mountain spotted fever | 0 | 1 (<0.1) | 1 (<0.1) |
| Sepsis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Sexually transmitted disease | 0 | 1 (<0.1) | 1 (<0.1) |
| Sialoadenitis | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Soft tissue infection | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Toxic shock syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaginal infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Viral pharyngitis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Viral rhinitis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Wound infection | 0 | 1 (<0.1) | 1 (<0.1) |
| Blastocystis infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Breast cellulitis | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.19.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Infections and infestations (Cont.) | | | |
| Campylobacter infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Conjunctivitis bacterial | 1 (<0.1) | 0 | 1 (<0.1) |
| Corneal infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Denture stomatitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Epididymitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Eye infection | 3 (<0.1) | 0 | 3 (<0.1) |
| Fungal skin infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Gardnerella infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastroenteritis viral | 2 (<0.1) | 0 | 2 (<0.1) |
| Genital herpes | 1 (<0.1) | 0 | 1 (<0.1) |
| Gonorrhoea | 1 (<0.1) | 0 | 1 (<0.1) |
| Mastoiditis | 1 (<0.1) | 0 | 1 (<0.1) |
| Nasopharyngitis | 4 (<0.1) | 0 | 4 (<0.1) |
| Pelvic abscess | 1 (<0.1) | 0 | 1 (<0.1) |
| Post procedural infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Root canal infection | 1 (<0.1) | 0 | 1 (<0.1) |
| Sinusitis bacterial | 1 (<0.1) | 0 | 1 (<0.1) |
| Streptococcal sepsis | 1 (<0.1) | 0 | 1 (<0.1) |
| Suspected COVID-19 | 2 (<0.1) | 0 | 2 (<0.1) |
| Syphilis | 1 (<0.1) | 0 | 1 (<0.1) |
| Tinea pedis | 2 (<0.1) | 0 | 2 (<0.1) |
| Tinea versicolour | 1 (<0.1) | 0 | 1 (<0.1) |
| Vulvovaginal mycotic infection | 6 (<0.1) | 0 | 6 (<0.1) |

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Table 14.3.1.19.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 29 (0.2) | 28 (0.2) | 57 (0.2) |
| Basal cell carcinoma | 11 (<0.1) | 5 (<0.1) | 16 (<0.1) |
| Squamous cell carcinoma | 5 (<0.1) | 3 (<0.1) | 8 (<0.1) |
| Malignant melanoma | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Melanocytic naevus | 0 | 2 (<0.1) | 2 (<0.1) |
| Prostate cancer | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Benign hepatic neoplasm | 0 | 1 (<0.1) | 1 (<0.1) |
| Benign neoplasm of thyroid gland | 0 | 1 (<0.1) | 1 (<0.1) |
| Breast neoplasm | 0 | 1 (<0.1) | 1 (<0.1) |
| Chronic lymphocytic leukaemia | 0 | 1 (<0.1) | 1 (<0.1) |
| Chronic myelomonocytic leukaemia | 0 | 1 (<0.1) | 1 (<0.1) |
| Lipoma | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Lung cancer metastatic | 0 | 1 (<0.1) | 1 (<0.1) |
| Nasopharyngeal neoplasm benign | 0 | 1 (<0.1) | 1 (<0.1) |
| Neoplasm malignant | 0 | 1 (<0.1) | 1 (<0.1) |
| Pelvic neoplasm | 0 | 1 (<0.1) | 1 (<0.1) |
| Rectal cancer | 0 | 1 (<0.1) | 1 (<0.1) |
| Skin papilloma | 0 | 1 (<0.1) | 1 (<0.1) |
| Thyroid cancer | 0 | 1 (<0.1) | 1 (<0.1) |
| Uterine leiomyoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Benign neoplasm of skin | 1 (<0.1) | 0 | 1 (<0.1) |
| Bladder neoplasm | 1 (<0.1) | 0 | 1 (<0.1) |
| Breast cancer | 1 (<0.1) | 0 | 1 (<0.1) |
| Breast cancer stage I | 1 (<0.1) | 0 | 1 (<0.1) |

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.) | | | |
| Chondromatosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Prolactin-producing pituitary tumour | 1 (<0.1) | 0 | 1 (<0.1) |
| Skin cancer | 1 (<0.1) | 0 | 1 (<0.1) |
| Squamous cell carcinoma of skin | 2 (<0.1) | 0 | 2 (<0.1) |
| Blood and lymphatic system disorders | 11 (<0.1) | 23 (0.2) | 34 (0.1) |
| Lymphadenopathy | 7 (<0.1) | 14 (<0.1) | 21 (<0.1) |
| Anaemia | 0 | 4 (<0.1) | 4 (<0.1) |
| Blood loss anaemia | 0 | 1 (<0.1) | 1 (<0.1) |
| Iron deficiency anaemia | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Leukocytosis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Splenomegaly | 0 | 1 (<0.1) | 1 (<0.1) |
| Thrombocytopenia | 0 | 1 (<0.1) | 1 (<0.1) |
| Lymphadenitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Immune system disorders | 7 (<0.1) | 5 (<0.1) | 12 (<0.1) |
| Seasonal allergy | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |
| Hypersensitivity | 0 | 1 (<0.1) | 1 (<0.1) |
| Allergy to plants | 1 (<0.1) | 0 | 1 (<0.1) |
| Anaphylactic reaction | 1 (<0.1) | 0 | 1 (<0.1) |
| Food allergy | 1 (<0.1) | 0 | 1 (<0.1) |
| Smoke sensitivity | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.19.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Endocrine disorders | 4 (<0.1) | 3 (<0.1) | 7 (<0.1) |
| Hypothyroidism | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Thyroid cyst | 0 | 1 (<0.1) | 1 (<0.1) |
| Androgen deficiency | 1 (<0.1) | 0 | 1 (<0.1) |
| Hypogonadism | 1 (<0.1) | 0 | 1 (<0.1) |
| Metabolism and nutrition disorders | 40 (0.3) | 38 (0.3) | 78 (0.3) |
| Type 2 diabetes mellitus | 1 (<0.1) | 8 (<0.1) | 9 (<0.1) |
| Hyperlipidaemia | 6 (<0.1) | 7 (<0.1) | 13 (<0.1) |
| Vitamin D deficiency | 1 (<0.1) | 5 (<0.1) | 6 (<0.1) |
| Dehydration | 4 (<0.1) | 3 (<0.1) | 7 (<0.1) |
| Hypercholesterolaemia | 9 (<0.1) | 3 (<0.1) | 12 (<0.1) |
| Decreased appetite | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Hyperglycaemia | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Hypertriglyceridaemia | 0 | 2 (<0.1) | 2 (<0.1) |
| Hyponatraemia | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Abnormal loss of weight | 0 | 1 (<0.1) | 1 (<0.1) |
| Diabetes mellitus | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Diabetes mellitus inadequate control | 0 | 1 (<0.1) | 1 (<0.1) |
| Gluten sensitivity | 0 | 1 (<0.1) | 1 (<0.1) |
| Gout | 5 (<0.1) | 1 (<0.1) | 6 (<0.1) |
| Hypokalaemia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Insulin resistance | 0 | 1 (<0.1) | 1 (<0.1) |
| Iron deficiency | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Magnesium deficiency | 0 | 1 (<0.1) | 1 (<0.1) |

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Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Metabolism and nutrition disorders (Cont.) | | | |
| Dyslipidaemia | 1 (<0.1) | 0 | 1 (<0.1) |
| Folate deficiency | 1 (<0.1) | 0 | 1 (<0.1) |
| Glucose tolerance impaired | 3 (<0.1) | 0 | 3 (<0.1) |
| Hypocalcaemia | 1 (<0.1) | 0 | 1 (<0.1) |
| Hypoglycaemia | 1 (<0.1) | 0 | 1 (<0.1) |
| Psychiatric disorders | 44 (0.3) | 46 (0.3) | 90 (0.3) |
| Depression | 11 (<0.1) | 19 (0.1) | 30 (<0.1) |
| Anxiety | 16 (0.1) | 18 (0.1) | 34 (0.1) |
| Attention deficit hyperactivity disorder | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |
| Alcohol withdrawal syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Anxiety disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Bipolar disorder | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Completed suicide | 0 | 1 (<0.1) | 1 (<0.1) |
| Drug use disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Insomnia | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Major depression | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Post-traumatic stress disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Schizoaffective disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Adjustment disorder with depressed mood | 1 (<0.1) | 0 | 1 (<0.1) |
| Alcohol abuse | 1 (<0.1) | 0 | 1 (<0.1) |
| Confusional state | 1 (<0.1) | 0 | 1 (<0.1) |
| Generalised anxiety disorder | 2 (<0.1) | 0 | 2 (<0.1) |
| Mental status changes | 2 (<0.1) | 0 | 2 (<0.1) |

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Psychiatric disorders (Cont.) | | | |
| Panic attack | 2 (<0.1) | 0 | 2 (<0.1) |
| Persistent depressive disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Psychotic disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Seasonal affective disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Stress | 1 (<0.1) | 0 | 1 (<0.1) |
| Nervous system disorders | 101 (0.7) | 105 (0.7) | 206 (0.7) |
| Headache | 54 (0.4) | 58 (0.4) | 112 (0.4) |
| Anosmia | 2 (<0.1) | 5 (<0.1) | 7 (<0.1) |
| Migraine | 4 (<0.1) | 5 (<0.1) | 9 (<0.1) |
| Dizziness | 8 (<0.1) | 4 (<0.1) | 12 (<0.1) |
| Paraesthesia | 5 (<0.1) | 4 (<0.1) | 9 (<0.1) |
| Sciatica | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |
| Carpal tunnel syndrome | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Syncope | 7 (<0.1) | 3 (<0.1) | 10 (<0.1) |
| Ageusia | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Cervical radiculopathy | 0 | 2 (<0.1) | 2 (<0.1) |
| Presyncope | 4 (<0.1) | 2 (<0.1) | 6 (<0.1) |
| Seizure | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Transient ischaemic attack | 0 | 2 (<0.1) | 2 (<0.1) |
| Amnesia | 0 | 1 (<0.1) | 1 (<0.1) |
| Balance disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Carotid artery stenosis | 0 | 1 (<0.1) | 1 (<0.1) |
| Cerebrovascular accident | 0 | 1 (<0.1) | 1 (<0.1) |

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Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Nervous system disorders (Cont.) | | | |
| Cubital tunnel syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Embolic stroke | 0 | 1 (<0.1) | 1 (<0.1) |
| Hyperaesthesia | 0 | 1 (<0.1) | 1 (<0.1) |
| Hyposmia | 0 | 1 (<0.1) | 1 (<0.1) |
| Lethargy | 0 | 1 (<0.1) | 1 (<0.1) |
| Memory impairment | 0 | 1 (<0.1) | 1 (<0.1) |
| Migraine without aura | 0 | 1 (<0.1) | 1 (<0.1) |
| Neuralgia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Primary headache associated with sexual activity | 0 | 1 (<0.1) | 1 (<0.1) |
| Sinus headache | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Small fibre neuropathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Tardive dyskinesia | 0 | 1 (<0.1) | 1 (<0.1) |
| Toxic encephalopathy | 0 | 1 (<0.1) | 1 (<0.1) |
| Basal ganglia haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Facial paralysis | 1 (<0.1) | 0 | 1 (<0.1) |
| Head discomfort | 1 (<0.1) | 0 | 1 (<0.1) |
| Horner's syndrome | 1 (<0.1) | 0 | 1 (<0.1) |
| Hypoaesthesia | 2 (<0.1) | 0 | 2 (<0.1) |
| Ischaemic stroke | 1 (<0.1) | 0 | 1 (<0.1) |
| Lumbar radiculopathy | 1 (<0.1) | 0 | 1 (<0.1) |
| Restless legs syndrome | 1 (<0.1) | 0 | 1 (<0.1) |
| Speech disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Tarsal tunnel syndrome | 1 (<0.1) | 0 | 1 (<0.1) |
| Tension headache | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.19.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Eye disorders | 20 (0.1) | 16 (0.1) | 36 (0.1) |
| Dry eye | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Retinal detachment | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Dry age-related macular degeneration | 0 | 1 (<0.1) | 1 (<0.1) |
| Eye discharge | 0 | 1 (<0.1) | 1 (<0.1) |
| Eye irritation | 0 | 1 (<0.1) | 1 (<0.1) |
| Eye pain | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Eye pruritus | 0 | 1 (<0.1) | 1 (<0.1) |
| Eyelid cyst | 0 | 1 (<0.1) | 1 (<0.1) |
| Glaucoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Noninfective conjunctivitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Ocular hyperaemia | 0 | 1 (<0.1) | 1 (<0.1) |
| Vision blurred | 0 | 1 (<0.1) | 1 (<0.1) |
| Vitreous disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Vitreous floaters | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Xerophthalmia | 0 | 1 (<0.1) | 1 (<0.1) |
| Blepharitis | 2 (<0.1) | 0 | 2 (<0.1) |
| Conjunctival haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Conjunctival irritation | 1 (<0.1) | 0 | 1 (<0.1) |
| Conjunctivitis allergic | 1 (<0.1) | 0 | 1 (<0.1) |
| Conjunctivochalasis | 1 (<0.1) | 0 | 1 (<0.1) |
| Dacryostenosis acquired | 1 (<0.1) | 0 | 1 (<0.1) |
| Eye swelling | 1 (<0.1) | 0 | 1 (<0.1) |
| Eyelid ptosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Lacrimation increased | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.19.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Eye disorders (Cont.) | | | |
| Macular degeneration | 1 (<0.1) | 0 | 1 (<0.1) |
| Macular hole | 1 (<0.1) | 0 | 1 (<0.1) |
| Periorbital swelling | 1 (<0.1) | 0 | 1 (<0.1) |
| Swelling of eyelid | 1 (<0.1) | 0 | 1 (<0.1) |
| Ulcerative keratitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Ear and labyrinth disorders | 17 (0.1) | 17 (0.1) | 34 (0.1) |
| Vertigo positional | 0 | 5 (<0.1) | 5 (<0.1) |
| Vertigo | 1 (<0.1) | 4 (<0.1) | 5 (<0.1) |
| Ear pain | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Cerumen impaction | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Deafness neurosensory | 0 | 1 (<0.1) | 1 (<0.1) |
| Ear canal erythema | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Middle ear effusion | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Motion sickness | 0 | 1 (<0.1) | 1 (<0.1) |
| Tinnitus | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Ear congestion | 2 (<0.1) | 0 | 2 (<0.1) |
| Eustachian tube dysfunction | 1 (<0.1) | 0 | 1 (<0.1) |
| Excessive cerumen production | 1 (<0.1) | 0 | 1 (<0.1) |
| Otorrhoea | 1 (<0.1) | 0 | 1 (<0.1) |
| Tympanic membrane perforation | 3 (<0.1) | 0 | 3 (<0.1) |
| Cardiac disorders | 25 (0.2) | 31 (0.2) | 56 (0.2) |
| Atrial fibrillation | 5 (<0.1) | 9 (<0.1) | 14 (<0.1) |

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Table 14.3.1.19.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Cardiac disorders (Cont.) | | | |
| Palpitations | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Cardiac failure congestive | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Coronary artery disease | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Myocardial infarction | 0 | 3 (<0.1) | 3 (<0.1) |
| Tachycardia | 4 (<0.1) | 3 (<0.1) | 7 (<0.1) |
| Angina pectoris | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Sinus tachycardia | 0 | 2 (<0.1) | 2 (<0.1) |
| Acute coronary syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Acute myocardial infarction | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Cardiac failure | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Cardio-respiratory arrest | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Cardiomyopathy | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Chronic left ventricular failure | 0 | 1 (<0.1) | 1 (<0.1) |
| Acute left ventricular failure | 1 (<0.1) | 0 | 1 (<0.1) |
| Arrhythmia | 3 (<0.1) | 0 | 3 (<0.1) |
| Atrial flutter | 1 (<0.1) | 0 | 1 (<0.1) |
| Atrial tachycardia | 1 (<0.1) | 0 | 1 (<0.1) |
| Cardiac failure acute | 1 (<0.1) | 0 | 1 (<0.1) |
| Ventricular extrasystoles | 1 (<0.1) | 0 | 1 (<0.1) |
| Ventricular fibrillation | 1 (<0.1) | 0 | 1 (<0.1) |
| Vascular disorders | 63 (0.4) | 63 (0.4) | 126 (0.4) |
| Hypertension | 48 (0.3) | 53 (0.3) | 101 (0.3) |
| Hypertensive urgency | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |

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Table 14.3.1.19.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Vascular disorders (Cont.) | | | |
| Achenbach syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Aortic aneurysm | 4 (<0.1) | 1 (<0.1) | 5 (<0.1) |
| Essential hypertension | 0 | 1 (<0.1) | 1 (<0.1) |
| Flushing | 0 | 1 (<0.1) | 1 (<0.1) |
| Haematoma | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Hot flush | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Hypotension | 0 | 1 (<0.1) | 1 (<0.1) |
| Peripheral artery occlusion | 0 | 1 (<0.1) | 1 (<0.1) |
| Systolic hypertension | 0 | 1 (<0.1) | 1 (<0.1) |
| Aortic stenosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Deep vein thrombosis | 2 (<0.1) | 0 | 2 (<0.1) |
| Fibromuscular dysplasia | 1 (<0.1) | 0 | 1 (<0.1) |
| Hypertensive emergency | 2 (<0.1) | 0 | 2 (<0.1) |
| Peripheral vascular disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Phlebitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Respiratory, thoracic and mediastinal disorders | 150 (1.0) | 129 (0.8) | 279 (0.9) |
| Cough | 56 (0.4) | 53 (0.3) | 109 (0.4) |
| Nasal congestion | 34 (0.2) | 47 (0.3) | 81 (0.3) |
| Rhinorrhoea | 34 (0.2) | 44 (0.3) | 78 (0.3) |
| Oropharyngeal pain | 46 (0.3) | 33 (0.2) | 79 (0.3) |
| Dyspnoea | 19 (0.1) | 19 (0.1) | 38 (0.1) |
| Asthma | 5 (<0.1) | 5 (<0.1) | 10 (<0.1) |
| Chronic obstructive pulmonary disease | 5 (<0.1) | 4 (<0.1) | 9 (<0.1) |

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Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Respiratory, thoracic and mediastinal disorders (Cont.) | | | |
| Respiratory tract congestion | 4 (<0.1) | 4 (<0.1) | 8 (<0.1) |
| Sinus congestion | 7 (<0.1) | 4 (<0.1) | 11 (<0.1) |
| Upper-airway cough syndrome | 1 (<0.1) | 4 (<0.1) | 5 (<0.1) |
| Dyspnoea exertional | 0 | 2 (<0.1) | 2 (<0.1) |
| Pulmonary embolism | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Rhinitis allergic | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Sneezing | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Throat irritation | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Wheezing | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Atelectasis | 0 | 1 (<0.1) | 1 (<0.1) |
| Dysphonia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Paranasal sinus discomfort | 0 | 1 (<0.1) | 1 (<0.1) |
| Pleurisy | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Pleuritic pain | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Productive cough | 0 | 1 (<0.1) | 1 (<0.1) |
| Respiratory disorder | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Sinus pain | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Tonsillolith | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Acute respiratory failure | 1 (<0.1) | 0 | 1 (<0.1) |
| Dry throat | 1 (<0.1) | 0 | 1 (<0.1) |
| Epistaxis | 1 (<0.1) | 0 | 1 (<0.1) |
| Laryngeal oedema | 1 (<0.1) | 0 | 1 (<0.1) |
| Paranasal sinus hypersecretion | 1 (<0.1) | 0 | 1 (<0.1) |

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Safety Set

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|--|-------------------------------|---------------------------------|-----------------------------|
| Respiratory, thoracic and mediastinal disorders (Cont.) | | | |
| Pharyngeal erythema | 1 (<0.1) | 0 | 1 (<0.1) |
| Pleural effusion | 1 (<0.1) | 0 | 1 (<0.1) |
| Pneumonia aspiration | 1 (<0.1) | 0 | 1 (<0.1) |
| Pneumonitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Pulmonary congestion | 1 (<0.1) | 0 | 1 (<0.1) |
| Pulmonary mass | 1 (<0.1) | 0 | 1 (<0.1) |
| Sinus polyp | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastrointestinal disorders | 111 (0.7) | 118 (0.8) | 229 (0.8) |
| Diarrhoea | 25 (0.2) | 31 (0.2) | 56 (0.2) |
| Nausea | 25 (0.2) | 27 (0.2) | 52 (0.2) |
| Gastrooesophageal reflux disease | 3 (<0.1) | 14 (<0.1) | 17 (<0.1) |
| Vomiting | 4 (<0.1) | 11 (<0.1) | 15 (<0.1) |
| Toothache | 9 (<0.1) | 10 (<0.1) | 19 (<0.1) |
| Abdominal pain | 7 (<0.1) | 5 (<0.1) | 12 (<0.1) |
| Abdominal pain upper | 2 (<0.1) | 5 (<0.1) | 7 (<0.1) |
| Constipation | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |
| Dental caries | 6 (<0.1) | 4 (<0.1) | 10 (<0.1) |
| Colitis | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Haematochezia | 0 | 3 (<0.1) | 3 (<0.1) |
| Inguinal hernia | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Anal fissure | 0 | 2 (<0.1) | 2 (<0.1) |
| Food poisoning | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |

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Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Gastrointestinal disorders (Cont.) | | | |
| Abdominal discomfort | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Abdominal hernia | 0 | 1 (<0.1) | 1 (<0.1) |
| Abdominal pain lower | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Diabetic gastroparesis | 0 | 1 (<0.1) | 1 (<0.1) |
| Diverticulum | 0 | 1 (<0.1) | 1 (<0.1) |
| Duodenal ulcer | 0 | 1 (<0.1) | 1 (<0.1) |
| Enteritis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Gastric ulcer | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Hiatus hernia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Hyperaesthesia teeth | 0 | 1 (<0.1) | 1 (<0.1) |
| Hyperchlorhydria | 0 | 1 (<0.1) | 1 (<0.1) |
| Hypoaesthesia oral | 0 | 1 (<0.1) | 1 (<0.1) |
| Impaired gastric emptying | 0 | 1 (<0.1) | 1 (<0.1) |
| Irritable bowel syndrome | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Large intestine perforation | 0 | 1 (<0.1) | 1 (<0.1) |
| Mouth ulceration | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Oesophageal ulcer | 0 | 1 (<0.1) | 1 (<0.1) |
| Oesophagitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Pancreatitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Pancreatitis acute | 0 | 1 (<0.1) | 1 (<0.1) |
| Paraesthesia oral | 0 | 1 (<0.1) | 1 (<0.1) |
| Proctalgia | 0 | 1 (<0.1) | 1 (<0.1) |
| Proctitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Rectal haemorrhage | 0 | 1 (<0.1) | 1 (<0.1) |

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Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Gastrointestinal disorders (Cont.) | | | |
| Salivary gland calculus | 0 | 1 (<0.1) | 1 (<0.1) |
| Salivary hypersecretion | 0 | 1 (<0.1) | 1 (<0.1) |
| Small intestinal obstruction | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Stomatitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Swollen tongue | 0 | 1 (<0.1) | 1 (<0.1) |
| Tooth impacted | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Umbilical hernia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Volvulus | 0 | 1 (<0.1) | 1 (<0.1) |
| Aphthous ulcer | 1 (<0.1) | 0 | 1 (<0.1) |
| Duodenal ulcer haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Dyspepsia | 2 (<0.1) | 0 | 2 (<0.1) |
| Femoral hernia | 1 (<0.1) | 0 | 1 (<0.1) |
| Flatulence | 1 (<0.1) | 0 | 1 (<0.1) |
| Gastritis | 2 (<0.1) | 0 | 2 (<0.1) |
| Gastrointestinal haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Intestinal obstruction | 1 (<0.1) | 0 | 1 (<0.1) |
| Large intestine polyp | 2 (<0.1) | 0 | 2 (<0.1) |
| Lip swelling | 1 (<0.1) | 0 | 1 (<0.1) |
| Loose tooth | 1 (<0.1) | 0 | 1 (<0.1) |
| Oral pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Palatal oedema | 1 (<0.1) | 0 | 1 (<0.1) |
| Retching | 1 (<0.1) | 0 | 1 (<0.1) |

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Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Hepatobiliary disorders | 0 | 10 (<0.1) | 10 (<0.1) |
| Cholelithiasis | 0 | 6 (<0.1) | 6 (<0.1) |
| Bile duct stone | 0 | 1 (<0.1) | 1 (<0.1) |
| Cholecystitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Cholecystitis acute | 0 | 1 (<0.1) | 1 (<0.1) |
| Hepatic mass | 0 | 1 (<0.1) | 1 (<0.1) |
| Skin and subcutaneous tissue disorders | 59 (0.4) | 60 (0.4) | 119 (0.4) |
| Dermatitis contact | 9 (<0.1) | 9 (<0.1) | 18 (<0.1) |
| Rash | 10 (<0.1) | 9 (<0.1) | 19 (<0.1) |
| Acne | 1 (<0.1) | 5 (<0.1) | 6 (<0.1) |
| Pruritus | 4 (<0.1) | 5 (<0.1) | 9 (<0.1) |
| Dermatitis | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Urticaria | 0 | 4 (<0.1) | 4 (<0.1) |
| Actinic keratosis | 0 | 2 (<0.1) | 2 (<0.1) |
| Neurodermatitis | 0 | 2 (<0.1) | 2 (<0.1) |
| Pityriasis rosea | 0 | 2 (<0.1) | 2 (<0.1) |
| Rosacea | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |
| Skin lesion | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Alopecia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Blister | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Dermal cyst | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Dermatitis allergic | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Dermatitis atopic | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Erythema | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |

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Table 14.3.1.19.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Skin and subcutaneous tissue disorders (Cont.) | | | |
| Hand dermatitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Hidradenitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Hyperhidrosis | 0 | 1 (<0.1) | 1 (<0.1) |
| Ingrowing nail | 0 | 1 (<0.1) | 1 (<0.1) |
| Lichen planus | 0 | 1 (<0.1) | 1 (<0.1) |
| Nail disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Rash erythematous | 0 | 1 (<0.1) | 1 (<0.1) |
| Rash pruritic | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Urticaria papular | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Angioedema | 3 (<0.1) | 0 | 3 (<0.1) |
| Cold sweat | 1 (<0.1) | 0 | 1 (<0.1) |
| Dermatitis bullous | 1 (<0.1) | 0 | 1 (<0.1) |
| Dry skin | 1 (<0.1) | 0 | 1 (<0.1) |
| Ecchymosis | 3 (<0.1) | 0 | 3 (<0.1) |
| Idiopathic urticaria | 1 (<0.1) | 0 | 1 (<0.1) |
| Ingrown hair | 1 (<0.1) | 0 | 1 (<0.1) |
| Lichenoid keratosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Livedo reticularis | 1 (<0.1) | 0 | 1 (<0.1) |
| Night sweats | 1 (<0.1) | 0 | 1 (<0.1) |
| Onychoclasia | 1 (<0.1) | 0 | 1 (<0.1) |
| Psoriasis | 1 (<0.1) | 0 | 1 (<0.1) |
| Scab | 1 (<0.1) | 0 | 1 (<0.1) |
| Seborrheic dermatitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Skin mass | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.19.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Musculoskeletal and connective tissue disorders | 126 (0.8) | 156 (1.0) | 282 (0.9) |
| Arthralgia | 23 (0.2) | 25 (0.2) | 48 (0.2) |
| Myalgia | 21 (0.1) | 23 (0.2) | 44 (0.1) |
| Back pain | 21 (0.1) | 18 (0.1) | 39 (0.1) |
| Neck pain | 2 (<0.1) | 12 (<0.1) | 14 (<0.1) |
| Musculoskeletal pain | 4 (<0.1) | 11 (<0.1) | 15 (<0.1) |
| Muscle spasms | 4 (<0.1) | 9 (<0.1) | 13 (<0.1) |
| Pain in extremity | 12 (<0.1) | 8 (<0.1) | 20 (<0.1) |
| Tendonitis | 7 (<0.1) | 8 (<0.1) | 15 (<0.1) |
| Arthritis | 1 (<0.1) | 4 (<0.1) | 5 (<0.1) |
| Intervertebral disc protrusion | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Musculoskeletal chest pain | 4 (<0.1) | 4 (<0.1) | 8 (<0.1) |
| Osteoarthritis | 8 (<0.1) | 4 (<0.1) | 12 (<0.1) |
| Rotator cuff syndrome | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |
| Bursitis | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Joint swelling | 0 | 3 (<0.1) | 3 (<0.1) |
| Musculoskeletal stiffness | 0 | 3 (<0.1) | 3 (<0.1) |
| Exostosis | 0 | 2 (<0.1) | 2 (<0.1) |
| Muscular weakness | 0 | 2 (<0.1) | 2 (<0.1) |
| Neck mass | 0 | 2 (<0.1) | 2 (<0.1) |
| Osteoporosis | 0 | 2 (<0.1) | 2 (<0.1) |
| Spinal stenosis | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Trigger finger | 0 | 2 (<0.1) | 2 (<0.1) |
| Bone pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Fibromyalgia | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |

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Table 14.3.1.19.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Musculoskeletal and connective tissue disorders (Cont.) | | | |
| Flank pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Floating patella | 0 | 1 (<0.1) | 1 (<0.1) |
| Groin pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Intervertebral disc degeneration | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Joint range of motion decreased | 0 | 1 (<0.1) | 1 (<0.1) |
| Joint stiffness | 0 | 1 (<0.1) | 1 (<0.1) |
| Limb discomfort | 0 | 1 (<0.1) | 1 (<0.1) |
| Muscle tightness | 0 | 1 (<0.1) | 1 (<0.1) |
| Muscle twitching | 0 | 1 (<0.1) | 1 (<0.1) |
| Osteopenia | 0 | 1 (<0.1) | 1 (<0.1) |
| Periarthritis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Plantar fasciitis | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Rheumatoid arthritis | 0 | 1 (<0.1) | 1 (<0.1) |
| Spinal osteoarthritis | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Spondylolysis | 0 | 1 (<0.1) | 1 (<0.1) |
| Tendon disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Axillary mass | 1 (<0.1) | 0 | 1 (<0.1) |
| Costochondritis | 3 (<0.1) | 0 | 3 (<0.1) |
| Femoroacetabular impingement | 1 (<0.1) | 0 | 1 (<0.1) |
| Intervertebral disc disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Myositis | 1 (<0.1) | 0 | 1 (<0.1) |
| Osteitis | 1 (<0.1) | 0 | 1 (<0.1) |
| Pain in jaw | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.19.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Musculoskeletal and connective tissue disorders (Cont.) | | | |
| Polymyalgia rheumatica | 1 (<0.1) | 0 | 1 (<0.1) |
| Synovial cyst | 1 (<0.1) | 0 | 1 (<0.1) |
| Vertebral foraminal stenosis | 1 (<0.1) | 0 | 1 (<0.1) |
| Renal and urinary disorders | 28 (0.2) | 21 (0.1) | 49 (0.2) |
| Nephrolithiasis | 18 (0.1) | 10 (<0.1) | 28 (<0.1) |
| Dysuria | 0 | 2 (<0.1) | 2 (<0.1) |
| Urinary hesitation | 0 | 2 (<0.1) | 2 (<0.1) |
| Acute kidney injury | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Chronic kidney disease | 0 | 1 (<0.1) | 1 (<0.1) |
| Cystitis interstitial | 0 | 1 (<0.1) | 1 (<0.1) |
| Haematuria | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Hydronephrosis | 0 | 1 (<0.1) | 1 (<0.1) |
| Lower urinary tract symptoms | 0 | 1 (<0.1) | 1 (<0.1) |
| Renal pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Ureterolithiasis | 0 | 1 (<0.1) | 1 (<0.1) |
| Urinary retention | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Bladder prolapse | 1 (<0.1) | 0 | 1 (<0.1) |
| Micturition urgency | 1 (<0.1) | 0 | 1 (<0.1) |
| Pollakiuria | 1 (<0.1) | 0 | 1 (<0.1) |
| Renal mass | 1 (<0.1) | 0 | 1 (<0.1) |
| Urge incontinence | 1 (<0.1) | 0 | 1 (<0.1) |
| Urinary incontinence | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.19.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Reproductive system and breast disorders | 16 (0.1) | 23 (0.2) | 39 (0.1) |
| Pelvic pain | 0 | 3 (<0.1) | 3 (<0.1) |
| Dysmenorrhoea | 0 | 2 (<0.1) | 2 (<0.1) |
| Adenomyosis | 0 | 1 (<0.1) | 1 (<0.1) |
| Balanoposthitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Benign prostatic hyperplasia | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Breast cyst | 0 | 1 (<0.1) | 1 (<0.1) |
| Breast disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Breast mass | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Breast pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Cervical dysplasia | 0 | 1 (<0.1) | 1 (<0.1) |
| Dysfunctional uterine bleeding | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Erectile dysfunction | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Menopausal symptoms | 0 | 1 (<0.1) | 1 (<0.1) |
| Nipple exudate bloody | 0 | 1 (<0.1) | 1 (<0.1) |
| Ovarian cyst | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Prostatitis | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Uterine haemorrhage | 0 | 1 (<0.1) | 1 (<0.1) |
| Uterine polyp | 0 | 1 (<0.1) | 1 (<0.1) |
| Vaginal discharge | 0 | 1 (<0.1) | 1 (<0.1) |
| Vulvovaginal pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Amenorrhoea | 1 (<0.1) | 0 | 1 (<0.1) |
| Bartholin's cyst | 1 (<0.1) | 0 | 1 (<0.1) |
| Cystocele | 1 (<0.1) | 0 | 1 (<0.1) |
| Endometriosis | 1 (<0.1) | 0 | 1 (<0.1) |

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Reproductive system and breast disorders (Cont.) | | | |
| Ovarian cyst ruptured | 2 (<0.1) | 0 | 2 (<0.1) |
| Uterine cyst | 1 (<0.1) | 0 | 1 (<0.1) |
| Congenital, familial and genetic disorders | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Arnold-Chiari malformation | 0 | 1 (<0.1) | 1 (<0.1) |
| Dermoid cyst | 0 | 1 (<0.1) | 1 (<0.1) |
| Hydrocele | 1 (<0.1) | 0 | 1 (<0.1) |
| General disorders and administration site conditions | 97 (0.6) | 100 (0.7) | 197 (0.6) |
| Fatigue | 49 (0.3) | 38 (0.3) | 87 (0.3) |
| Pain | 10 (<0.1) | 18 (0.1) | 28 (<0.1) |
| Chills | 12 (<0.1) | 14 (<0.1) | 26 (<0.1) |
| Pyrexia | 13 (<0.1) | 11 (<0.1) | 24 (<0.1) |
| Injection site erythema | 0 | 9 (<0.1) | 9 (<0.1) |
| Injection site pain | 3 (<0.1) | 7 (<0.1) | 10 (<0.1) |
| Injection site induration | 0 | 6 (<0.1) | 6 (<0.1) |
| Chest discomfort | 5 (<0.1) | 4 (<0.1) | 9 (<0.1) |
| Injection site rash | 0 | 4 (<0.1) | 4 (<0.1) |
| Injection site swelling | 0 | 3 (<0.1) | 3 (<0.1) |
| Non-cardiac chest pain | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Swelling face | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Chest pain | 4 (<0.1) | 2 (<0.1) | 6 (<0.1) |
| Oedema peripheral | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |

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Table 14.3.1.19.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| General disorders and administration site conditions (Cont.) | | | |
| Adverse drug reaction | 0 | 1 (<0.1) | 1 (<0.1) |
| Axillary pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Crying | 0 | 1 (<0.1) | 1 (<0.1) |
| Cyst | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Feeling hot | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Granuloma | 0 | 1 (<0.1) | 1 (<0.1) |
| Induration | 0 | 1 (<0.1) | 1 (<0.1) |
| Inflammation | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site pruritus | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Injection site warmth | 0 | 1 (<0.1) | 1 (<0.1) |
| Injury associated with device | 0 | 1 (<0.1) | 1 (<0.1) |
| Malaise | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Nodule | 0 | 1 (<0.1) | 1 (<0.1) |
| Peripheral swelling | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Vessel puncture site haematoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Asthenia | 2 (<0.1) | 0 | 2 (<0.1) |
| Facial pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Gait disturbance | 1 (<0.1) | 0 | 1 (<0.1) |
| Hangover | 1 (<0.1) | 0 | 1 (<0.1) |
| Incarcerated hernia | 1 (<0.1) | 0 | 1 (<0.1) |
| Injection site bruising | 1 (<0.1) | 0 | 1 (<0.1) |
| Pelvic mass | 1 (<0.1) | 0 | 1 (<0.1) |
| Precancerous condition | 2 (<0.1) | 0 | 2 (<0.1) |

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Table 14.3.1.19.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Investigations | 22 (0.1) | 24 (0.2) | 46 (0.2) |
| Hepatic enzyme increased | 0 | 3 (<0.1) | 3 (<0.1) |
| Blood pressure increased | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Blood pressure systolic increased | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Hormone level abnormal | 0 | 2 (<0.1) | 2 (<0.1) |
| Transaminases increased | 0 | 2 (<0.1) | 2 (<0.1) |
| Aspartate aminotransferase increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Blood cholesterol increased | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Blood glucose decreased | 0 | 1 (<0.1) | 1 (<0.1) |
| Blood pressure diastolic increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Blood triglycerides increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Cardiac murmur | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Electrocardiogram T wave inversion | 0 | 1 (<0.1) | 1 (<0.1) |
| Fibrin D dimer increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Glycosylated haemoglobin increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Heart rate irregular | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Hepatic enzyme abnormal | 0 | 1 (<0.1) | 1 (<0.1) |
| Influenza A virus test positive | 0 | 1 (<0.1) | 1 (<0.1) |
| Neutrophil count increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Oxygen saturation decreased | 0 | 1 (<0.1) | 1 (<0.1) |
| Prostatic specific antigen increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Thyroid function test abnormal | 0 | 1 (<0.1) | 1 (<0.1) |
| Alanine aminotransferase increased | 1 (<0.1) | 0 | 1 (<0.1) |
| Biopsy skin | 1 (<0.1) | 0 | 1 (<0.1) |
| Blood glucose increased | 1 (<0.1) | 0 | 1 (<0.1) |

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--|-------------------------------|---------------------------------|-----------------------------|
| Investigations (Cont.) | | | |
| Blood iron decreased | 2 (<0.1) | 0 | 2 (<0.1) |
| Blood potassium decreased | 1 (<0.1) | 0 | 1 (<0.1) |
| Brain natriuretic peptide increased | 1 (<0.1) | 0 | 1 (<0.1) |
| Colonoscopy | 1 (<0.1) | 0 | 1 (<0.1) |
| Heart rate increased | 1 (<0.1) | 0 | 1 (<0.1) |
| Lipase increased | 1 (<0.1) | 0 | 1 (<0.1) |
| Mammogram abnormal | 1 (<0.1) | 0 | 1 (<0.1) |
| SARS-CoV-2 test positive | 3 (<0.1) | 0 | 3 (<0.1) |
| Vitamin B12 decreased | 1 (<0.1) | 0 | 1 (<0.1) |
| Vitamin D decreased | 1 (<0.1) | 0 | 1 (<0.1) |
| Injury, poisoning and procedural complications | 140 (0.9) | 139 (0.9) | 279 (0.9) |
| Skin laceration | 22 (0.1) | 17 (0.1) | 39 (0.1) |
| Ligament sprain | 6 (<0.1) | 14 (<0.1) | 20 (<0.1) |
| Muscle strain | 10 (<0.1) | 12 (<0.1) | 22 (<0.1) |
| Foot fracture | 6 (<0.1) | 8 (<0.1) | 14 (<0.1) |
| Limb injury | 4 (<0.1) | 8 (<0.1) | 12 (<0.1) |
| Arthropod bite | 5 (<0.1) | 7 (<0.1) | 12 (<0.1) |
| Fall | 5 (<0.1) | 6 (<0.1) | 11 (<0.1) |
| Procedural pain | 6 (<0.1) | 6 (<0.1) | 12 (<0.1) |
| Concussion | 3 (<0.1) | 5 (<0.1) | 8 (<0.1) |
| Tooth fracture | 7 (<0.1) | 5 (<0.1) | 12 (<0.1) |
| Hand fracture | 1 (<0.1) | 4 (<0.1) | 5 (<0.1) |
| Meniscus injury | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) |

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Table 14.3.1.19.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Injury, poisoning and procedural complications (Cont.) | | | |
| Animal bite | 5 (<0.1) | 3 (<0.1) | 8 (<0.1) |
| Arthropod sting | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) |
| Contusion | 8 (<0.1) | 3 (<0.1) | 11 (<0.1) |
| Rib fracture | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Cartilage injury | 0 | 2 (<0.1) | 2 (<0.1) |
| Cervical vertebral fracture | 0 | 2 (<0.1) | 2 (<0.1) |
| Epicondylitis | 0 | 2 (<0.1) | 2 (<0.1) |
| Facial bones fracture | 0 | 2 (<0.1) | 2 (<0.1) |
| Head injury | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Ligament rupture | 0 | 2 (<0.1) | 2 (<0.1) |
| Muscle rupture | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Tendon rupture | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Upper limb fracture | 0 | 2 (<0.1) | 2 (<0.1) |
| Wrist fracture | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Alcohol poisoning | 0 | 1 (<0.1) | 1 (<0.1) |
| Animal scratch | 0 | 1 (<0.1) | 1 (<0.1) |
| Ankle fracture | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Back injury | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Bone fragmentation | 0 | 1 (<0.1) | 1 (<0.1) |
| Burns first degree | 0 | 1 (<0.1) | 1 (<0.1) |
| Burns second degree | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Clavicle fracture | 0 | 1 (<0.1) | 1 (<0.1) |
| Corneal abrasion | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |

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Percentages are based on the number of safety subjects.

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Table 14.3.1.19.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Injury, poisoning and procedural complications (Cont.) | | | |
| Craniocerebral injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Femoral neck fracture | 0 | 1 (<0.1) | 1 (<0.1) |
| Fibula fracture | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Hip fracture | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Joint dislocation | 0 | 1 (<0.1) | 1 (<0.1) |
| Ligament injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Lower limb fracture | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Lumbar vertebral fracture | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Meniscus cyst | 0 | 1 (<0.1) | 1 (<0.1) |
| Nasal injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Overdose | 0 | 1 (<0.1) | 1 (<0.1) |
| Patella fracture | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Periorbital haematoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Periorbital haemorrhage | 0 | 1 (<0.1) | 1 (<0.1) |
| Post procedural haemorrhage | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Post-traumatic neck syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Road traffic accident | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Scar | 0 | 1 (<0.1) | 1 (<0.1) |
| Subdural haematoma | 0 | 1 (<0.1) | 1 (<0.1) |
| Tendon injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Thermal burn | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Tooth injury | 0 | 1 (<0.1) | 1 (<0.1) |

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Table 14.3.1.19.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|---|-------------------------------|---------------------------------|-----------------------------|
| Injury, poisoning and procedural complications (Cont.) | | | |
| Traumatic liver injury | 0 | 1 (<0.1) | 1 (<0.1) |
| Abdominal injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Bone contusion | 1 (<0.1) | 0 | 1 (<0.1) |
| Exposure to SARS-CoV-2 | 1 (<0.1) | 0 | 1 (<0.1) |
| Eye injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Foreign body | 2 (<0.1) | 0 | 2 (<0.1) |
| Foreign body in ear | 1 (<0.1) | 0 | 1 (<0.1) |
| Iliotibial band syndrome | 1 (<0.1) | 0 | 1 (<0.1) |
| Immunisation anxiety related reaction | 1 (<0.1) | 0 | 1 (<0.1) |
| Injection related reaction | 1 (<0.1) | 0 | 1 (<0.1) |
| Joint injury | 2 (<0.1) | 0 | 2 (<0.1) |
| Post procedural haematoma | 1 (<0.1) | 0 | 1 (<0.1) |
| Post-traumatic pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Procedural haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Respiratory fume inhalation disorder | 1 (<0.1) | 0 | 1 (<0.1) |
| Scratch | 1 (<0.1) | 0 | 1 (<0.1) |
| Skin abrasion | 5 (<0.1) | 0 | 5 (<0.1) |
| Stress fracture | 3 (<0.1) | 0 | 3 (<0.1) |
| Superficial injury of eye | 1 (<0.1) | 0 | 1 (<0.1) |
| Tibia fracture | 1 (<0.1) | 0 | 1 (<0.1) |
| Ulna fracture | 1 (<0.1) | 0 | 1 (<0.1) |
| Ulnar nerve injury | 1 (<0.1) | 0 | 1 (<0.1) |
| Wound | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.19.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Surgical and medical procedures | 10 (<0.1) | 12 (<0.1) | 22 (<0.1) |
| Endodontic procedure | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Ankle arthroplasty | 0 | 1 (<0.1) | 1 (<0.1) |
| Cholecystectomy | 0 | 1 (<0.1) | 1 (<0.1) |
| Curettage of chalazion | 0 | 1 (<0.1) | 1 (<0.1) |
| Cyst removal | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Dental operation | 0 | 1 (<0.1) | 1 (<0.1) |
| Lipoma excision | 0 | 1 (<0.1) | 1 (<0.1) |
| Phlebectomy | 0 | 1 (<0.1) | 1 (<0.1) |
| Skin neoplasm excision | 0 | 1 (<0.1) | 1 (<0.1) |
| Thyroidectomy | 0 | 1 (<0.1) | 1 (<0.1) |
| Transurethral prostatectomy | 0 | 1 (<0.1) | 1 (<0.1) |
| Carpal tunnel decompression | 1 (<0.1) | 0 | 1 (<0.1) |
| Cataract operation | 1 (<0.1) | 0 | 1 (<0.1) |
| Fracture treatment | 1 (<0.1) | 0 | 1 (<0.1) |
| Hip arthroplasty | 1 (<0.1) | 0 | 1 (<0.1) |
| Tooth extraction | 1 (<0.1) | 0 | 1 (<0.1) |
| Tooth repair | 2 (<0.1) | 0 | 2 (<0.1) |
| Umbilical hernia repair | 1 (<0.1) | 0 | 1 (<0.1) |
| Social circumstances | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Menopause | 0 | 1 (<0.1) | 1 (<0.1) |
| Sexual abuse | 1 (<0.1) | 0 | 1 (<0.1) |

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Table 14.3.1.19.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

| System Organ Class Preferred Term | Placebo (N=15165) n (%) | mRNA-1273 (N=15184) n (%) | Total (N=30350) n (%) |
|--------------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Product issues | 2 (<0.1) | 4 (<0.1) | 6 (<0.1) |
| Device breakage | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Device dislocation | 0 | 1 (<0.1) | 1 (<0.1) |
| Embedded device | 0 | 1 (<0.1) | 1 (<0.1) |
| Lead dislodgement | 1 (<0.1) | 0 | 1 (<0.1) |
| Uncoded | 59 (0.4) | 63 (0.4) | 122 (0.4) |
| Uncoded | 59 (0.4) | 63 (0.4) | 122 (0.4) |

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Percentages are based on the number of safety subjects.

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