

Table 14.1.1.1.2.2
Subject Disposition by Age Group
Full Analysis Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|--|--------------------|-----------------|-----------------|----------------|----------------|----------------|-----------------|-----------------|-----------------|
| | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total |
| | (N=11418) | (N=11413) | (N=22831) | (N=3752) | (N=3768) | (N=7520) | (N=15170) | (N=15181) | (N=30351) |
| | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| Number of Subjects | | | | | | | | | |
| Received First Injection | 11418 (100) | 11413 (100) | 22831 (100) | 3752 (100) | 3768 (100) | 7520 (100) | 15170 (100) | 15181 (100) | 30351 (100) |
| Received Second Injection | 10950 (95.9) | 11009 (96.5) | 21959 (96.2) | 3667 (97.7) | 3702 (98.2) | 7369 (98.0) | 14617 (96.4) | 14711 (96.9) | 29328 (96.6) |
| Discontinued Study Vaccine | 227 (2.0) | 187 (1.6) | 414 (1.8) | 47 (1.3) | 32 (0.8) | 79 (1.1) | 274 (1.8) | 219 (1.4) | 493 (1.6) |
| Reason for Discontinuation of Study Vaccine | | | | | | | | | |
| Adverse Event | 18 (0.2) | 20 (0.2) | 38 (0.2) | 7 (0.2) | 8 (0.2) | 15 (0.2) | 25 (0.2) | 28 (0.2) | 53 (0.2) |
| Serious Adverse Event | 6 (<0.1) | 7 (<0.1) | 13 (<0.1) | 9 (0.2) | 2 (<0.1) | 11 (0.1) | 15 (<0.1) | 9 (<0.1) | 24 (<0.1) |
| Death | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) |
| Lost to Follow-Up | 24 (0.2) | 26 (0.2) | 50 (0.2) | 0 (0.2) | 1 (<0.1) | 1 (<0.1) | 24 (0.2) | 27 (0.2) | 51 (0.2) |
| Physician Decision | 7 (<0.1) | 13 (0.1) | 20 (<0.1) | 0 (<0.1) | 1 (<0.1) | 1 (<0.1) | 7 (<0.1) | 14 (<0.1) | 21 (<0.1) |
| Pregnancy | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) | 0 (<0.1) | 0 (<0.1) | 0 (<0.1) | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Protocol Deviation | 4 (<0.1) | 2 (<0.1) | 6 (<0.1) | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) | 5 (<0.1) | 3 (<0.1) | 8 (<0.1) |

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

[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 14.1.1.1.2.2
Subject Disposition by Age Group
Full Analysis Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|--|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=11418) | mRNA-1273 (N=11413) | Total (N=22831) | Placebo (N=3752) | mRNA-1273 (N=3768) | Total (N=7520) | Placebo (N=15170) | mRNA-1273 (N=15181) | Total (N=30351) |
| | 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 | 71 (0.6) | 41 (0.4) | 112 (0.5) | 18 (0.5) | 11 (0.3) | 29 (0.4) | 89 (0.6) | 52 (0.3) | 141 (0.5) |
| Due to SARS-CoV-2 | 63 (0.6) | 40 (0.4) | 103 (0.5) | 6 (0.2) | 5 (0.1) | 11 (0.1) | 69 (0.5) | 45 (0.3) | 114 (0.4) |
| Other | 31 (0.3) | 34 (0.3) | 65 (0.3) | 4 (0.1) | 2 (<0.1) | 6 (<0.1) | 35 (0.2) | 36 (0.2) | 71 (0.2) |
| Completed Study [1] | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Discontinued from Study | 153 (1.3) | 123 (1.1) | 276 (1.2) | 30 (0.8) | 19 (0.5) | 49 (0.7) | 183 (1.2) | 142 (0.9) | 325 (1.1) |
| Reason for Discontinuation of Study | | | | | | | | | |
| Adverse Event | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) | 0 | 1 (<0.1) | 1 (<0.1) | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Serious Adverse Event | 0 | 2 (<0.1) | 2 (<0.1) | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |

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

[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 14.1.1.1.2.2
Subject Disposition by Age Group
Full Analysis Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|--|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=11418) | mRNA-1273 (N=11413) | Total (N=22831) | Placebo (N=3752) | mRNA-1273 (N=3768) | Total (N=7520) | Placebo (N=15170) | mRNA-1273 (N=15181) | Total (N=30351) |
| | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| Reason for Discontinuation of Study (Cont.) | | | | | | | | | |
| Death | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) | 6 (<0.1) | 4 (<0.1) | 10 (<0.1) |
| Lost to Follow-Up | 35 (0.3) | 32 (0.3) | 67 (0.3) | 0 | 1 (<0.1) | 1 (<0.1) | 35 (0.2) | 33 (0.2) | 68 (0.2) |
| Physician Decision | 2 (<0.1) | 13 (0.1) | 15 (<0.1) | 0 | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) | 14 (<0.1) | 16 (<0.1) |
| Pregnancy | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Protocol Deviation | 0 | 1 (<0.1) | 1 (<0.1) | 0 | 0 | 0 | 0 | 1 (<0.1) | 1 (<0.1) |
| Study Terminated by Sponsor | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Withdrawal of Consent by Participant | 108 (0.9) | 65 (0.6) | 173 (0.8) | 24 (0.6) | 13 (0.3) | 37 (0.5) | 132 (0.9) | 78 (0.5) | 210 (0.7) |
| Other | 4 (<0.1) | 6 (<0.1) | 10 (<0.1) | 1 (<0.1) | 0 | 1 (<0.1) | 5 (<0.1) | 6 (<0.1) | 11 (<0.1) |

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

[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 14.1.1.1.3.2
Subject Disposition by Age Group
Per-Protocol Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|--|--------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total |
| | (N=10521) | (N=10551) | (N=21072) | (N=3552) | (N=3583) | (N=7135) | (N=14073) | (N=14134) | (N=28207) |
| | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| Number of Subjects | | | | | | | | | |
| Received First Injection | 10521 (100) | 10551 (100) | 21072 (100) | 3552 (100) | 3583 (100) | 7135 (100) | 14073 (100) | 14134 (100) | 28207 (100) |
| Received Second Injection | 10474 (99.6) | 10522 (99.7) | 20996 (99.6) | 3551 (>99.9) | 3582 (>99.9) | 7133 (>99.9) | 14025 (99.7) | 14104 (99.8) | 28129 (99.7) |
| Discontinued Study Vaccine | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Reason for Discontinuation of Study Vaccine | | | | | | | | | |
| Adverse Event | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Serious Adverse Event | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Death | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Lost to Follow-Up | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Physician Decision | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pregnancy | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Protocol Deviation | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Percentages are based on the number of subjects in Per-Protocol Set.

[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 14.1.1.1.3.2
Subject Disposition by Age Group
Per-Protocol Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|--|-------------------------------|---------------------------------|-----------------------------|------------------------------|--------------------------------|----------------------------|-------------------------------|---------------------------------|-----------------------------|
| | Placebo (N=10521) n (%) | mRNA-1273 (N=10551) n (%) | Total (N=21072) n (%) | Placebo (N=3552) n (%) | mRNA-1273 (N=3583) n (%) | Total (N=7135) n (%) | Placebo (N=14073) n (%) | mRNA-1273 (N=14134) n (%) | Total (N=28207) 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 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Due to SARS-CoV-2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Other | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Completed Study [1] | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Discontinued from Study | 44 (0.4) | 33 (0.3) | 77 (0.4) | 7 (0.2) | 3 (<0.1) | 10 (0.1) | 51 (0.4) | 36 (0.3) | 87 (0.3) |
| Reason for Discontinuation of Study | | | | | | | | | |
| Adverse Event | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Serious Adverse Event | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Percentages are based on the number of subjects in Per-Protocol Set.

[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 14.1.1.1.3.2
Subject Disposition by Age Group
Per-Protocol Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|---|--------------------|-------------|--------------|-------------|-------------|-------------|--------------|-------------|--------------|
| | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total |
| | (N=10521) | (N=10551) | (N=21072) | (N=3552) | (N=3583) | (N=7135) | (N=14073) | (N=14134) | (N=28207) |
| | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| Reason for Discontinuation of Study (Cont.) | | | | | | | | | |
| Death | 2 (<0.1) | 0 | 2 (<0.1) | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) | 1 (<0.1) | 4 (<0.1) |
| Lost to Follow-Up | 10 (<0.1) | 5 (<0.1) | 15 (<0.1) | 0 | 0 | 0 | 10 (<0.1) | 5 (<0.1) | 15 (<0.1) |
| Physician Decision | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) | 0 | 1 (<0.1) | 1 (<0.1) | 1 (<0.1) | 3 (<0.1) | 4 (<0.1) |
| Pregnancy | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Protocol Deviation | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Study Terminated by Sponsor | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Withdrawal of Consent by Participant | 30 (0.3) | 24 (0.2) | 54 (0.3) | 5 (0.1) | 1 (<0.1) | 6 (<0.1) | 35 (0.2) | 25 (0.2) | 60 (0.2) |
| Other | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) | 1 (<0.1) | 0 | 1 (<0.1) | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) |

Percentages are based on the number of subjects in Per-Protocol Set.

[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 14.1.2.1
Number of Subjects in Each Analysis Set by Baseline SARS-CoV-2 Status
Randomization Set

| | Baseline SARS-CoV-2 Negative | | | Baseline SARS-CoV-2 Positive | | | Overall | | |
|---|------------------------------|------------------|------------------|------------------------------|---------------|---------------|------------------|------------------|------------------|
| | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total |
| Randomization Set [1] | 14598 | 14550 | 29148 | 337 | 343 | 680 | 15210 | 15210 | 30420 |
| Full Analysis Set, n (%) [1] | 14598 (100) | 14550 (100) | 29148 (100) | 337 (100) | 343 (100) | 680 (100) | 15170 (99.7) | 15181 (99.8) | 30351 (99.8) |
| Modified Intent-to-Treat (mITT) Set, n (%) [1] | 14598 (100) | 14550 (100) | 29148 (100) | 0 | 0 | 0 | 14598 (96.0) | 14550 (95.7) | 29148 (95.8) |
| Per-Protocol (PP) Set, n (%) [1] | 14073 (96.4) | 14134 (97.1) | 28207 (96.8) | 0 | 0 | 0 | 14073 (92.5) | 14134 (92.9) | 28207 (92.7) |
| Safety Set [2] | 14594 | 14554 | 29148 | 337 | 343 | 680 | 15166 | 15185 | 30351 |
| Solicited Safety Set, n (%) [2] | 14591 (>99.9) | 14548 (>99.9) | 29139 (>99.9) | 337 (100) | 343 (100) | 680 (100) | 15163 (>99.9) | 15179 (>99.9) | 30342 (>99.9) |
| First Injection Solicited Safety Set, n (%) [2] | 14583 (>99.9) | 14538 (99.9) | 29121 (>99.9) | 337 (100) | 342 (99.7) | 679 (99.9) | 15155 (>99.9) | 15168 (99.9) | 30323 (>99.9) |
| Second Injection Solicited Safety Set, n (%) [2] | 14119 (96.7) | 14183 (97.5) | 28302 (97.1) | 232 (68.8) | 230 (67.1) | 462 (67.9) | 14566 (96.0) | 14677 (96.7) | 29243 (96.3) |

[1] Numbers are based on planned treatment group and percentages are based on the number of randomized subjects.

[2] Numbers are based on actual treatment group and percentages are based on the number of safety subjects.

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Table 14.1.2.2
Number of Subjects in Each Analysis Set by Age Group
Randomization Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|---|--------------------|------------------|------------------|-----------------|-----------------|-----------------|------------------|------------------|------------------|
| | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total |
| Randomization Set [1] | 11448 | 11439 | 22887 | 3762 | 3771 | 7533 | 15210 | 15210 | 30420 |
| Full Analysis Set, n (%) [1] | 11418 (99.7) | 11413 (99.8) | 22831 (99.8) | 3752 (99.7) | 3768 (>99.9) | 7520 (99.8) | 15170 (99.7) | 15181 (99.8) | 30351 (99.8) |
| Modified Intent-to-Treat (mITT) Set, n (%) [1] | 10944 (95.6) | 10890 (95.2) | 21834 (95.4) | 3654 (97.1) | 3660 (97.1) | 7314 (97.1) | 14598 (96.0) | 14550 (95.7) | 29148 (95.8) |
| Per-Protocol (PP) Set, n (%) [1] | 10521 (91.9) | 10551 (92.2) | 21072 (92.1) | 3552 (94.4) | 3583 (95.0) | 7135 (94.7) | 14073 (92.5) | 14134 (92.9) | 28207 (92.7) |
| Safety Set [2] | 11416 | 11415 | 22831 | 3750 | 3770 | 7520 | 15166 | 15185 | 30351 |
| Solicited Safety Set, n (%) [2] | 11413 (>99.9) | 11412 (>99.9) | 22825 (>99.9) | 3750 (100) | 3767 (>99.9) | 7517 (>99.9) | 15163 (>99.9) | 15179 (>99.9) | 30342 (>99.9) |
| First Injection Solicited Safety Set, n (%) [2] | 11407 (>99.9) | 11406 (>99.9) | 22813 (>99.9) | 3748 (>99.9) | 3762 (99.8) | 7510 (99.9) | 15155 (>99.9) | 15168 (99.9) | 30323 (>99.9) |
| Second Injection Solicited Safety Set, n (%) [2] | 10918 (95.6) | 10985 (96.2) | 21903 (95.9) | 3648 (97.3) | 3692 (97.9) | 7340 (97.6) | 14566 (96.0) | 14677 (96.7) | 29243 (96.3) |

[1] Numbers are based on planned treatment group and percentages are based on the number of randomized subjects.

[2] Numbers are based on actual treatment group and percentages are based on the number of safety subjects.

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|-------------------------------|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=10521) | mRNA-1273 (N=10551) | Total (N=21072) | Placebo (N=3552) | mRNA-1273 (N=3583) | Total (N=7135) | Placebo (N=14073) | mRNA-1273 (N=14134) | Total (N=28207) |
| Age at Screening (Years) | | | | | | | | | |
| n | 10521 | 10551 | 21072 | 3552 | 3583 | 7135 | 14073 | 14134 | 28207 |
| Mean | 45.1 | 45.2 | 45.2 | 70.7 | 70.4 | 70.6 | 51.6 | 51.6 | 51.6 |
| (SD) | (12.24) | (12.29) | (12.27) | (4.84) | (4.64) | (4.74) | (15.54) | (15.44) | (15.49) |
| Median | 46.0 | 46.0 | 46.0 | 70.0 | 69.0 | 70.0 | 52.0 | 53.0 | 53.0 |
| 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 | 10521 (100) | 10551 (100) | 21072 (100) | 0 | 0 | 0 | 10521 (74.8) | 10551 (74.6) | 21072 (74.7) |
| Mean | 45.1 | 45.2 | 45.2 | | | | 45.1 | 45.2 | 45.2 |
| (SD) | (12.24) | (12.29) | (12.27) | | | | (12.24) | (12.29) | (12.27) |
| Median | 46.0 | 46.0 | 46.0 | | | | 46.0 | 46.0 | 46.0 |
| Min, Max | 18, 64 | 18, 64 | 18, 64 | | | | 18, 64 | 18, 64 | 18, 64 |
| >=65 Years | 0 | 0 | 0 | 3552 (100) | 3583 (100) | 7135 (100) | 3552 (25.2) | 3583 (25.4) | 7135 (25.3) |
| Mean | | | | 70.7 | 70.4 | 70.6 | 70.7 | 70.4 | 70.6 |
| (SD) | | | | (4.84) | (4.64) | (4.74) | (4.84) | (4.64) | (4.74) |
| Median | | | | 70.0 | 69.0 | 70.0 | 70.0 | 69.0 | 70.0 |
| Min, Max | | | | 65, 95 | 65, 95 | 65, 95 | 65, 95 | 65, 95 | 65, 95 |

Note: Footnotes are listed on the last page.

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|-------------------------------------|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=10521) | mRNA-1273 (N=10551) | Total (N=21072) | Placebo (N=3552) | mRNA-1273 (N=3583) | Total (N=7135) | Placebo (N=14073) | mRNA-1273 (N=14134) | Total (N=28207) |
| Age Subgroup at Screening, n (%) | | | | | | | | | |
| >=18 and <65 Years | 10521 (100) | 10551 (100) | 21072 (100) | 0 | 0 | 0 | 10521 (74.8) | 10551 (74.6) | 21072 (74.7) |
| >=65 and <70 Years | 0 | 0 | 0 | 1724 (48.5) | 1809 (50.5) | 3533 (49.5) | 1724 (12.3) | 1809 (12.8) | 3533 (12.5) |
| >=70 and <75 Years | 0 | 0 | 0 | 1140 (32.1) | 1144 (31.9) | 2284 (32.0) | 1140 (8.1) | 1144 (8.1) | 2284 (8.1) |
| >=75 and <80 Years | 0 | 0 | 0 | 474 (13.3) | 450 (12.6) | 924 (13.0) | 474 (3.4) | 450 (3.2) | 924 (3.3) |
| >=80 Years | 0 | 0 | 0 | 214 (6.0) | 180 (5.0) | 394 (5.5) | 214 (1.5) | 180 (1.3) | 394 (1.4) |
| Age Subgroup at Screening, n (%) | | | | | | | | | |
| >=18 and <65 Years | 10521 (100) | 10551 (100) | 21072 (100) | 0 | 0 | 0 | 10521 (74.8) | 10551 (74.6) | 21072 (74.7) |
| >=65 and <75 Years | 0 | 0 | 0 | 2864 (80.6) | 2953 (82.4) | 5817 (81.5) | 2864 (20.4) | 2953 (20.9) | 5817 (20.6) |
| >=75 and <85 Years | 0 | 0 | 0 | 642 (18.1) | 593 (16.6) | 1235 (17.3) | 642 (4.6) | 593 (4.2) | 1235 (4.4) |
| >=85 Years | 0 | 0 | 0 | 46 (1.3) | 37 (1.0) | 83 (1.2) | 46 (0.3) | 37 (0.3) | 83 (0.3) |

Note: Footnotes are listed on the last page.

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|---|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=10521) | mRNA-1273 (N=10551) | Total (N=21072) | Placebo (N=3552) | mRNA-1273 (N=3583) | Total (N=7135) | Placebo (N=14073) | mRNA-1273 (N=14134) | Total (N=28207) |
| Age and Health Risk for Severe COVID-19, n (%) [1] | | | | | | | | | |
| >=18 and <65 Years and Not at Risk | 8199 (77.9) | 8189 (77.6) | 16388 (77.8) | 1 (<0.1) | 0 | 1 (<0.1) | 8200 (58.3) | 8189 (57.9) | 16389 (58.1) |
| >=18 and <65 Years and at Risk | 2321 (22.1) | 2361 (22.4) | 4682 (22.2) | 3 (<0.1) | 6 (0.2) | 9 (0.1) | 2324 (16.5) | 2367 (16.7) | 4691 (16.6) |
| >=65 Years | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) | 3548 (99.9) | 3577 (99.8) | 7125 (99.9) | 3549 (25.2) | 3578 (25.3) | 7127 (25.3) |
| Risk Factor for Severe COVID-19 at Screening, n (%) [2] | | | | | | | | | |
| Chronic Lung Disease | 462 (4.4) | 448 (4.2) | 910 (4.3) | 226 (6.4) | 225 (6.3) | 451 (6.3) | 688 (4.9) | 673 (4.8) | 1361 (4.8) |
| Significant Cardiac Disease | 273 (2.6) | 293 (2.8) | 566 (2.7) | 421 (11.9) | 418 (11.7) | 839 (11.8) | 694 (4.9) | 711 (5.0) | 1405 (5.0) |
| Severe Obesity | 805 (7.7) | 804 (7.6) | 1609 (7.6) | 131 (3.7) | 152 (4.2) | 283 (4.0) | 936 (6.7) | 956 (6.8) | 1892 (6.7) |
| Diabetes | 835 (7.9) | 859 (8.1) | 1694 (8.0) | 510 (14.4) | 505 (14.1) | 1015 (14.2) | 1345 (9.6) | 1364 (9.7) | 2709 (9.6) |
| Liver Disease | 65 (0.6) | 79 (0.7) | 144 (0.7) | 25 (0.7) | 16 (0.4) | 41 (0.6) | 90 (0.6) | 95 (0.7) | 185 (0.7) |
| Human Immunodeficiency Virus Infection | 63 (0.6) | 68 (0.6) | 131 (0.6) | 14 (0.4) | 14 (0.4) | 28 (0.4) | 77 (0.5) | 82 (0.6) | 159 (0.6) |

Note: Footnotes are listed on the last page.

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|---|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=10521) | mRNA-1273 (N=10551) | Total (N=21072) | Placebo (N=3552) | mRNA-1273 (N=3583) | Total (N=7135) | Placebo (N=14073) | mRNA-1273 (N=14134) | Total (N=28207) |
| At Risk for Severe COVID-19 at Screening, n (%) | | | | | | | | | |
| Yes | 2118 (20.1) | 2155 (20.4) | 4273 (20.3) | 1049 (29.5) | 1051 (29.3) | 2100 (29.4) | 3167 (22.5) | 3206 (22.7) | 6373 (22.6) |
| One Risk Factor for Severe COVID-19 | 1780 (16.9) | 1808 (17.1) | 3588 (17.0) | 811 (22.8) | 808 (22.6) | 1619 (22.7) | 2591 (18.4) | 2616 (18.5) | 5207 (18.5) |
| Two or More Risk Factors for Severe COVID-19 | 338 (3.2) | 347 (3.3) | 685 (3.3) | 238 (6.7) | 243 (6.8) | 481 (6.7) | 576 (4.1) | 590 (4.2) | 1166 (4.1) |
| No | 8403 (79.9) | 8396 (79.6) | 16799 (79.7) | 2503 (70.5) | 2532 (70.7) | 5035 (70.6) | 10906 (77.5) | 10928 (77.3) | 21834 (77.4) |
| Age and Risk for Severe COVID-19, n (%) [3] | | | | | | | | | |
| >=18 and <65 Years and Not at Risk | 8403 (79.9) | 8396 (79.6) | 16799 (79.7) | 0 | 0 | 0 | 8403 (59.7) | 8396 (59.4) | 16799 (59.6) |
| >=18 and <65 Years and at Risk | 2118 (20.1) | 2155 (20.4) | 4273 (20.3) | 0 | 0 | 0 | 2118 (15.1) | 2155 (15.2) | 4273 (15.1) |
| >=65 Years and Not at Risk | 0 | 0 | 0 | 2503 (70.5) | 2532 (70.7) | 5035 (70.6) | 2503 (17.8) | 2532 (17.9) | 5035 (17.9) |
| >=65 Years and at Risk | 0 | 0 | 0 | 1049 (29.5) | 1051 (29.3) | 2100 (29.4) | 1049 (7.5) | 1051 (7.4) | 2100 (7.4) |

Note: Footnotes are listed on the last page.

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|--|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=10521) | mRNA-1273 (N=10551) | Total (N=21072) | Placebo (N=3552) | mRNA-1273 (N=3583) | Total (N=7135) | Placebo (N=14073) | mRNA-1273 (N=14134) | Total (N=28207) |
| Baseline RT-PCR Results, n (%) | | | | | | | | | |
| Negative | 10521 (100) | 10551 (100) | 21072 (100) | 3552 (100) | 3583 (100) | 7135 (100) | 14073 (100) | 14134 (100) | 28207 (100) |
| Positive | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Baseline Elecsys Anti-SARS-CoV-2 Results, n (%) | | | | | | | | | |
| Negative | 10521 (100) | 10551 (100) | 21072 (100) | 3552 (100) | 3583 (100) | 7135 (100) | 14073 (100) | 14134 (100) | 28207 (100) |
| Positive | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Baseline SARS-CoV-2 Status, n (%) [4] | | | | | | | | | |
| Negative | 10521 (100) | 10551 (100) | 21072 (100) | 3552 (100) | 3583 (100) | 7135 (100) | 14073 (100) | 14134 (100) | 28207 (100) |
| Positive | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Note: Footnotes are listed on the last page.

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|---|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=10521) | mRNA-1273 (N=10551) | Total (N=21072) | Placebo (N=3552) | mRNA-1273 (N=3583) | Total (N=7135) | Placebo (N=14073) | mRNA-1273 (N=14134) | Total (N=28207) |
| Sex, n (%) | | | | | | | | | |
| Male | 5471 (52.0) | 5386 (51.0) | 10857 (51.5) | 1991 (56.1) | 1980 (55.3) | 3971 (55.7) | 7462 (53.0) | 7366 (52.1) | 14828 (52.6) |
| Female | 5050 (48.0) | 5165 (49.0) | 10215 (48.5) | 1561 (43.9) | 1603 (44.7) | 3164 (44.3) | 6611 (47.0) | 6768 (47.9) | 13379 (47.4) |
| Race, n (%) | | | | | | | | | |
| White | 8004 (76.1) | 8037 (76.2) | 16041 (76.1) | 3170 (89.2) | 3216 (89.8) | 6386 (89.5) | 11174 (79.4) | 11253 (79.6) | 22427 (79.5) |
| Black or African American | 1157 (11.0) | 1182 (11.2) | 2339 (11.1) | 192 (5.4) | 203 (5.7) | 395 (5.5) | 1349 (9.6) | 1385 (9.8) | 2734 (9.7) |
| Asian | 616 (5.9) | 555 (5.3) | 1171 (5.6) | 73 (2.1) | 65 (1.8) | 138 (1.9) | 689 (4.9) | 620 (4.4) | 1309 (4.6) |
| American Indian or Alaska Native | 87 (0.8) | 87 (0.8) | 174 (0.8) | 24 (0.7) | 21 (0.6) | 45 (0.6) | 111 (0.8) | 108 (0.8) | 219 (0.8) |
| Native Hawaiian or Other Pacific Islander | 28 (0.3) | 32 (0.3) | 60 (0.3) | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) | 31 (0.2) | 35 (0.2) | 66 (0.2) |
| Multiracial | 270 (2.6) | 263 (2.5) | 533 (2.5) | 37 (1.0) | 32 (0.9) | 69 (1.0) | 307 (2.2) | 295 (2.1) | 602 (2.1) |
| Other | 262 (2.5) | 273 (2.6) | 535 (2.5) | 33 (0.9) | 26 (0.7) | 59 (0.8) | 295 (2.1) | 299 (2.1) | 594 (2.1) |
| Not Reported | 52 (0.5) | 73 (0.7) | 125 (0.6) | 12 (0.3) | 13 (0.4) | 25 (0.4) | 64 (0.5) | 86 (0.6) | 150 (0.5) |
| Unknown | 45 (0.4) | 49 (0.5) | 94 (0.4) | 8 (0.2) | 4 (0.1) | 12 (0.2) | 53 (0.4) | 53 (0.4) | 106 (0.4) |

Note: Footnotes are listed on the last page.

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|---------------------------------|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=10521) | mRNA-1273 (N=10551) | Total (N=21072) | Placebo (N=3552) | mRNA-1273 (N=3583) | Total (N=7135) | Placebo (N=14073) | mRNA-1273 (N=14134) | Total (N=28207) |
| Ethnicity, n (%) | | | | | | | | | |
| Hispanic or Latino | 2476 (23.5) | 2463 (23.3) | 4939 (23.4) | 304 (8.6) | 326 (9.1) | 630 (8.8) | 2780 (19.8) | 2789 (19.7) | 5569 (19.7) |
| Not Hispanic or Latino | 7960 (75.7) | 7998 (75.8) | 15958 (75.7) | 3205 (90.2) | 3214 (89.7) | 6419 (90.0) | 11165 (79.3) | 11212 (79.3) | 22377 (79.3) |
| Not Reported | 49 (0.5) | 65 (0.6) | 114 (0.5) | 27 (0.8) | 32 (0.9) | 59 (0.8) | 76 (0.5) | 97 (0.7) | 173 (0.6) |
| Unknown | 36 (0.3) | 25 (0.2) | 61 (0.3) | 16 (0.5) | 11 (0.3) | 27 (0.4) | 52 (0.4) | 36 (0.3) | 88 (0.3) |
| Race and Ethnicity Group, n (%) | | | | | | | | | |
| [5] | | | | | | | | | |
| Minority | 3634 (34.5) | 3632 (34.4) | 7266 (34.5) | 506 (14.2) | 532 (14.8) | 1038 (14.5) | 4140 (29.4) | 4164 (29.5) | 8304 (29.4) |
| Non-minority | 6875 (65.3) | 6902 (65.4) | 13777 (65.4) | 3033 (85.4) | 3045 (85.0) | 6078 (85.2) | 9908 (70.4) | 9947 (70.4) | 19855 (70.4) |
| Missing | 12 (0.1) | 17 (0.2) | 29 (0.1) | 13 (0.4) | 6 (0.2) | 19 (0.3) | 25 (0.2) | 23 (0.2) | 48 (0.2) |
| Race and Ethnicity Group, n (%) | | | | | | | | | |
| [6] | | | | | | | | | |
| White | 5994 (57.0) | 6089 (57.7) | 12083 (57.3) | 2922 (82.3) | 2934 (81.9) | 5856 (82.1) | 8916 (63.4) | 9023 (63.8) | 17939 (63.6) |
| Communities of Color | 4515 (42.9) | 4445 (42.1) | 8960 (42.5) | 617 (17.4) | 643 (17.9) | 1260 (17.7) | 5132 (36.5) | 5088 (36.0) | 10220 (36.2) |
| Missing | 12 (0.1) | 17 (0.2) | 29 (0.1) | 13 (0.4) | 6 (0.2) | 19 (0.3) | 25 (0.2) | 23 (0.2) | 48 (0.2) |

Note: Footnotes are listed on the last page.

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|--------------------------------------|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=10521) | mRNA-1273 (N=10551) | Total (N=21072) | Placebo (N=3552) | mRNA-1273 (N=3583) | Total (N=7135) | Placebo (N=14073) | mRNA-1273 (N=14134) | Total (N=28207) |
| Weight (kg) | | | | | | | | | |
| n | 10424 | 10446 | 20870 | 3523 | 3543 | 7066 | 13947 | 13989 | 27936 |
| Mean | 86.66 | 86.50 | 86.58 | 83.13 | 83.08 | 83.10 | 85.77 | 85.63 | 85.70 |
| (SD) | (22.357) | (22.689) | (22.524) | (18.966) | (19.325) | (19.146) | (21.605) | (21.936) | (21.771) |
| Median | 83.64 | 83.64 | 83.64 | 81.36 | 81.20 | 81.36 | 82.80 | 83.00 | 82.98 |
| Min, Max | 27.1, 216.5 | 30.3, 236.4 | 27.1, 236.4 | 34.8, 184.5 | 31.5, 165.0 | 31.5, 184.5 | 27.1, 216.5 | 30.3, 236.4 | 27.1, 236.4 |
| Height (cm) | | | | | | | | | |
| n | 10424 | 10446 | 20870 | 3522 | 3544 | 7066 | 13946 | 13990 | 27936 |
| Mean | 171.22 | 170.99 | 171.11 | 170.08 | 170.04 | 170.06 | 170.93 | 170.75 | 170.84 |
| (SD) | (9.968) | (9.902) | (9.936) | (10.173) | (9.952) | (10.062) | (10.032) | (9.923) | (9.978) |
| Median | 171.00 | 170.20 | 170.70 | 170.18 | 170.18 | 170.18 | 170.64 | 170.18 | 170.20 |
| Min, Max | 118.0, 205.7 | 104.1, 221.0 | 104.1, 221.0 | 124.5, 223.5 | 123.0, 208.3 | 123.0, 223.5 | 118.0, 223.5 | 104.1, 221.0 | 104.1, 223.5 |
| Body Mass Index (kg/m ²) | | | | | | | | | |
| n | 10423 | 10443 | 20866 | 3522 | 3543 | 7065 | 13945 | 13986 | 27931 |
| Mean | 29.47 | 29.50 | 29.49 | 28.66 | 28.63 | 28.65 | 29.27 | 29.28 | 29.28 |
| (SD) | (6.889) | (7.113) | (7.002) | (5.843) | (5.857) | (5.849) | (6.650) | (6.827) | (6.739) |
| Median | 28.23 | 28.22 | 28.23 | 27.68 | 27.86 | 27.76 | 28.08 | 28.10 | 28.09 |
| Min, Max | 10.3, 72.7 | 11.2, 82.0 | 10.3, 82.0 | 12.1, 71.1 | 12.8, 62.9 | 12.1, 71.1 | 10.3, 72.7 | 11.2, 82.0 | 10.3, 82.0 |

Note: Footnotes are listed on the last page.

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|--|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=10521) | mRNA-1273 (N=10551) | Total (N=21072) | Placebo (N=3552) | mRNA-1273 (N=3583) | Total (N=7135) | Placebo (N=14073) | mRNA-1273 (N=14134) | Total (N=28207) |
| Occupational Risk, n (%) [2] | 9337 (88.7) | 9333 (88.5) | 18670 (88.6) | 2253 (63.4) | 2253 (62.9) | 4506 (63.2) | 11590 (82.4) | 11586 (82.0) | 23176 (82.2) |
| Healthcare Workers | 3111 (29.6) | 3150 (29.9) | 6261 (29.7) | 470 (13.2) | 443 (12.4) | 913 (12.8) | 3581 (25.4) | 3593 (25.4) | 7174 (25.4) |
| Emergency Response | 256 (2.4) | 263 (2.5) | 519 (2.5) | 17 (0.5) | 21 (0.6) | 38 (0.5) | 273 (1.9) | 284 (2.0) | 557 (2.0) |
| Retail or Restaurant Operations | 780 (7.4) | 757 (7.2) | 1537 (7.3) | 91 (2.6) | 98 (2.7) | 189 (2.6) | 871 (6.2) | 855 (6.0) | 1726 (6.1) |
| Manufacturing and Production Operations | 362 (3.4) | 349 (3.3) | 711 (3.4) | 25 (0.7) | 32 (0.9) | 57 (0.8) | 387 (2.7) | 381 (2.7) | 768 (2.7) |
| Warehouse Shipping and Fulfillment Centers | 146 (1.4) | 164 (1.6) | 310 (1.5) | 11 (0.3) | 9 (0.3) | 20 (0.3) | 157 (1.1) | 173 (1.2) | 330 (1.2) |
| Transportation and Delivery Services | 368 (3.5) | 381 (3.6) | 749 (3.6) | 58 (1.6) | 43 (1.2) | 101 (1.4) | 426 (3.0) | 424 (3.0) | 850 (3.0) |
| Border Protection and Military Personnel | 60 (0.6) | 62 (0.6) | 122 (0.6) | 4 (0.1) | 3 (<0.1) | 7 (<0.1) | 64 (0.5) | 65 (0.5) | 129 (0.5) |
| Personal Care and In-Home Services | 358 (3.4) | 344 (3.3) | 702 (3.3) | 54 (1.5) | 65 (1.8) | 119 (1.7) | 412 (2.9) | 409 (2.9) | 821 (2.9) |
| Hospitality and Tourism Workers | 161 (1.5) | 180 (1.7) | 341 (1.6) | 41 (1.2) | 31 (0.9) | 72 (1.0) | 202 (1.4) | 211 (1.5) | 413 (1.5) |
| Pastoral, Social or Public Health Workers | 341 (3.2) | 356 (3.4) | 697 (3.3) | 136 (3.8) | 138 (3.9) | 274 (3.8) | 477 (3.4) | 494 (3.5) | 971 (3.4) |
| Educators and Students | 1302 (12.4) | 1277 (12.1) | 2579 (12.2) | 164 (4.6) | 179 (5.0) | 343 (4.8) | 1466 (10.4) | 1456 (10.3) | 2922 (10.4) |
| Other | 3110 (29.6) | 3156 (29.9) | 6266 (29.7) | 1352 (38.1) | 1365 (38.1) | 2717 (38.1) | 4462 (31.7) | 4521 (32.0) | 8983 (31.8) |

Note: Footnotes are listed on the last page.

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

| | >=18 and <65 Years | | | >=65 Years | | | Overall | | |
|-------------------------------|----------------------|------------------------|--------------------|---------------------|-----------------------|-------------------|----------------------|------------------------|--------------------|
| | Placebo (N=10521) | mRNA-1273 (N=10551) | Total (N=21072) | Placebo (N=3552) | mRNA-1273 (N=3583) | Total (N=7135) | Placebo (N=14073) | mRNA-1273 (N=14134) | Total (N=28207) |
| Location and Living | 8771 | 8809 | 17580 | 2920 | 2974 | 5894 | 11691 | 11783 | 23474 |
| Circumstances Risk, n (%) [2] | (83.4) | (83.5) | (83.4) | (82.2) | (83.0) | (82.6) | (83.1) | (83.4) | (83.2) |
| Resides in Nursing Home or | 9 | 19 | 28 | 19 | 10 | 29 | 28 | 29 | 57 |
| 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 | 313 | 352 | 665 | 61 | 63 | 124 | 374 | 415 | 789 |
| Dwelling | (3.0) | (3.3) | (3.2) | (1.7) | (1.8) | (1.7) | (2.7) | (2.9) | (2.8) |
| Resides in High Density | 955 | 939 | 1894 | 226 | 234 | 460 | 1181 | 1173 | 2354 |
| Housing | (9.1) | (8.9) | (9.0) | (6.4) | (6.5) | (6.4) | (8.4) | (8.3) | (8.3) |
| Resides in Low Density, | 1103 | 1114 | 2217 | 240 | 232 | 472 | 1343 | 1346 | 2689 |
| Multi-Family Setting | (10.5) | (10.6) | (10.5) | (6.8) | (6.5) | (6.6) | (9.5) | (9.5) | (9.5) |
| Resides in a Single Family | 5671 | 5651 | 11322 | 2126 | 2178 | 4304 | 7797 | 7829 | 15626 |
| Home | (53.9) | (53.6) | (53.7) | (59.9) | (60.8) | (60.3) | (55.4) | (55.4) | (55.4) |
| Other | 1514 | 1537 | 3051 | 495 | 516 | 1011 | 2009 | 2053 | 4062 |
| | (14.4) | (14.6) | (14.5) | (13.9) | (14.4) | (14.2) | (14.3) | (14.5) | (14.4) |

Note: Footnotes are listed on the last page.

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

Percentages are based on the number of subjects in Per-Protocol 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] Age and health risk for severe COVID-19 are derived from age and risk factors collected on case report form (CRF).
- [4] 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.
- [5] 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.
- [6] 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.

Table 14.1.6.4
Summary of Study Duration
Per-Protocol Set

| | Placebo (N=14073) | mRNA-1273 (N=14134) | Total (N=28207) |
|--|----------------------|------------------------|--------------------|
| Number of Subjects, n (%) | | | |
| Received First Injection | 14073 (100) | 14134 (100) | 28207 (100) |
| Received Second Injection | 14025 (99.7) | 14104 (99.8) | 28129 (99.7) |
| >= 49 Days Since First Injection | 13173 (93.6) | 13217 (93.5) | 26390 (93.6) |
| >= 56 Days Since First Injection | 12862 (91.4) | 12930 (91.5) | 25792 (91.4) |
| >= 2 Months Since First Injection | 12605 (89.6) | 12702 (89.9) | 25307 (89.7) |
| >= 28 Days Since Second Injection | 12786 (90.9) | 12881 (91.1) | 25667 (91.0) |
| >= 56 Days Since Second Injection | 8987 (63.9) | 9102 (64.4) | 18089 (64.1) |
| >= 2 Months Since Second Injection | 7849 (55.8) | 7903 (55.9) | 15752 (55.8) |
| < 28 Days Since Second Injection | 1239 (8.8) | 1223 (8.7) | 2462 (8.7) |
| >= 28 and < 56 Days Since Second Injection | 3799 (27.0) | 3779 (26.7) | 7578 (26.9) |
| >= 56 Days Since Second Injection | 8987 (63.9) | 9102 (64.4) | 18089 (64.1) |
| Study Duration from Randomization (Days) | | | |
| Mean (SD) | 89.2 (20.49) | 89.4 (20.40) | 89.3 (20.45) |
| Median | 93.0 | 93.0 | 93.0 |
| Q1, Q3 | 78.0, 105.0 | 78.0, 105.0 | 78.0, 105.0 |
| Min, Max | 29, 122 | 29, 122 | 29, 122 |
| Study Duration from First Injection (Days) | | | |
| Mean (SD) | 89.2 (20.50) | 89.4 (20.40) | 89.3 (20.45) |
| Median | 93.0 | 93.0 | 93.0 |
| Q1, Q3 | 78.0, 105.0 | 78.0, 105.0 | 78.0, 105.0 |
| Min, Max | 29, 122 | 29, 122 | 29, 122 |

1 month = 30.4375 days.

Percentages are based on the number of subjects in Per-Protocol Set.

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

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Table 14.1.6.4
Summary of Study Duration
Per-Protocol Set

| | Placebo (N=14073) | mRNA-1273 (N=14134) | Total (N=28207) |
|--|----------------------|------------------------|--------------------|
| Study Duration from Second Injection (Days) [1] | | | |
| Mean (SD) | 60.0 (20.56) | 60.2 (20.46) | 60.1 (20.51) |
| Median | 63.0 | 64.0 | 64.0 |
| Q1, Q3 | 49.0, 76.0 | 49.0, 76.0 | 49.0, 76.0 |
| Min, Max | 0, 97 | 0, 97 | 0, 97 |
| Study Duration from Second Injection in Subjects Who Received Second Injection (Days) | | | |
| n | 14025 | 14104 | 28129 |
| Mean (SD) | 60.2 (20.29) | 60.3 (20.30) | 60.2 (20.30) |
| Median | 64.0 | 64.0 | 64.0 |
| Q1, Q3 | 49.0, 76.0 | 49.0, 76.0 | 49.0, 76.0 |
| Min, Max | 1, 97 | 1, 97 | 1, 97 |

1 month = 30.4375 days.

Percentages are based on the number of subjects in Per-Protocol Set.

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

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Table 14.2.1.1.1.1.1
Summary of Primary and Secondary Efficacy Endpoint Analysis Results
Per-Protocol Set

| | Placebo (N=14073) | mRNA-1273 (N=14134) |
|--|----------------------|--------------------------------|
| COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection | | |
| Number of Events | 185 | 11 |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] p-value [2] | | 0.941 (0.893, 0.968) <.0001 |
| COVID-19 Starting 14 Days After Second Injection | | |
| Number of Events | 202 | 11 |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.947 (0.902, 0.971) |
| Severe COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection | | |
| Number of Events | 30 | 0 |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 1.000 (NE, 1.000) |
| Severe COVID-19 Starting 14 Days After Second Injection | | |
| Number of Events | 38 | 0 |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 1.000 (NE, 1.000) |
| Secondary Definition of COVID-19 Starting 14 Days After Second Injection | | |
| Number of Events | 221 | 11 |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.951 (0.911, 0.973) |

[1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] 1-sided p-value from stratified Cox proportional hazard model to test the null hypothesis $VE \leq 0.3$.

[3] n and N are based on the number of subjects in the Full Analysis Set.

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Table 14.2.1.1.1.1.1
Summary of Primary and Secondary Efficacy Endpoint Analysis Results
Per-Protocol Set

| | Placebo (N=14073) | mRNA-1273 (N=14134) |
|--|----------------------|------------------------|
| Death Caused by COVID-19 Starting 14 Days After Second Injection | | |
| Number of Events | 1 | 0 |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 1.000 (NE, 1.000) |
| COVID-19 Starting 14 Days After First Injection | | |
| Number of Events | 225 | 11 |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.952 (0.912, 0.974) |
| COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection Regardless of Prior SARS-CoV-2 Infection, n/N [3] | | |
| Number of Events | 187/15170 | 12/15181 |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.936 (0.886, 0.965) |
| COVID-19 Starting 14 Days After Second Injection Regardless of Prior SARS-CoV-2 Infection, n/N [3] | | |
| Number of Events | 207/15170 | 12/15181 |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.943 (0.898, 0.968) |

[1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] 1-sided p-value from stratified Cox proportional hazard model to test the null hypothesis $VE \leq 0.3$.

[3] n and N are based on the number of subjects in the Full Analysis Set.

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Table 14.2.2.1.1.1.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days
After Second Injection
Per-Protocol Set

| | Placebo (N=14073) | mRNA-1273 (N=14134) |
|--|-------------------------|--------------------------------|
| Number of Subjects with COVID-19, n (%) | 185 (1.3) | 11 (<0.1) |
| Number of Subjects Censored, n (%) | 13888 (98.7) | 14123 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] p-value [2] | | 0.941 (0.893, 0.968) <.0001 |
| Person-Years [3] | 3273.7 | 3304.9 |
| Incidence Rate per 1,000 Person-Years (95% CI) [4] | 56.510 (48.660, 65.266) | 3.328 (1.662, 5.955) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [5] | | 0.941 (0.892, 0.971) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
- [2] 1-sided p-value from stratified Cox proportional hazard model to test the null hypothesis $VE \leq 0.3$.
- [3] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [4] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [5] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.1.2
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days
After Second Injection
mITT Set

| | Placebo (N=14598) | mRNA-1273 (N=14550) |
|---|-------------------------|------------------------|
| Number of Subjects with COVID-19, n (%) | 185 (1.3) | 12 (<0.1) |
| Number of Subjects Censored, n (%) | 14413 (98.7) | 14538 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.936 (0.885, 0.964) |
| Person-Years [2] | 3382.9 | 3390.1 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 54.688 (47.091, 63.161) | 3.540 (1.829, 6.183) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.935 (0.884, 0.967) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.1.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (≥ 18 and < 65 Years, ≥ 65 Years)
Per-Protocol Set

Age Group: ≥ 18 and < 65 Years

| | Placebo (N=10521) | mRNA-1273 (N=10551) |
|---|-------------------------|------------------------|
| Number of Subjects with COVID-19, n (%) | 156 (1.5) | 7 (<0.1) |
| Number of Subjects Censored, n (%) | 10365 (98.5) | 10544 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.956 (0.906, 0.979) |
| Person-Years [2] | 2413.9 | 2434.5 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 64.625 (54.882, 75.599) | 2.875 (1.156, 5.924) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.956 (0.906, 0.982) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.1.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (≥ 18 and < 65 Years, ≥ 65 Years)
Per-Protocol Set

Age Group: ≥ 65 Years

| | Placebo (N=3552) | mRNA-1273 (N=3583) |
|---|-------------------------|-----------------------|
| Number of Subjects with COVID-19, n (%) | 29 (0.8) | 4 (0.1) |
| Number of Subjects Censored, n (%) | 3523 (99.2) | 3579 (99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.864 (0.614, 0.952) |
| Person-Years [2] | 859.8 | 870.5 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 33.728 (22.588, 48.439) | 4.595 (1.252, 11.766) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.864 (0.612, 0.965) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.2.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (≥ 18 and < 65 Years, ≥ 65 and < 75 Years, ≥ 75 Years)
Per-Protocol Set

Age Group: ≥ 18 and < 65 Years

| | Placebo (N=10521) | mRNA-1273 (N=10551) |
|---|-------------------------|------------------------|
| Number of Subjects with COVID-19, n (%) | 156 (1.5) | 7 (<0.1) |
| Number of Subjects Censored, n (%) | 10365 (98.5) | 10544 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.956 (0.906, 0.979) |
| Person-Years [2] | 2413.9 | 2434.5 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 64.625 (54.882, 75.599) | 2.875 (1.156, 5.924) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.956 (0.906, 0.982) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.2.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (≥ 18 and < 65 Years, ≥ 65 and < 75 Years, ≥ 75 Years)
Per-Protocol Set

Age Group: ≥ 65 and < 75 Years

| | Placebo (N=2864) | mRNA-1273 (N=2953) |
|---|-------------------------|-----------------------|
| Number of Subjects with COVID-19, n (%) | 22 (0.8) | 4 (0.1) |
| Number of Subjects Censored, n (%) | 2842 (99.2) | 2949 (99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.824 (0.489, 0.939) |
| Person-Years [2] | 693.0 | 716.0 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 31.744 (19.894, 48.061) | 5.586 (1.522, 14.303) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.824 (0.482, 0.956) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.2.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (≥ 18 and < 65 Years, ≥ 65 and < 75 Years, ≥ 75 Years)
Per-Protocol Set

Age Group: ≥ 75 Years

| | Placebo (N=688) | mRNA-1273 (N=630) |
|---|-------------------------|----------------------|
| Number of Subjects with COVID-19, n (%) | 7 (1.0) | 0 |
| Number of Subjects Censored, n (%) | 681 (99.0) | 630 (100) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 1.000 (NE, 1.000) |
| Person-Years [2] | 166.8 | 154.4 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 41.968 (16.873, 86.471) | 0.000 (NE, 23.884) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 1.000 (0.251, NE) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.3.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19
Per-Protocol Set

Age and Health Risk for Severe COVID-19: ≥ 18 and < 65 Years and Not at Risk

| | Placebo (N=8403) | mRNA-1273 (N=8396) |
|---|-------------------------|-----------------------|
| Number of Subjects with COVID-19, n (%) | 121 (1.4) | 5 (<0.1) |
| Number of Subjects Censored, n (%) | 8282 (98.6) | 8391 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.959 (0.900, 0.983) |
| Person-Years [2] | 1919.0 | 1927.7 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 63.054 (52.321, 75.342) | 2.594 (0.842, 6.053) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.959 (0.901, 0.987) |

Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.3.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19
Per-Protocol Set

Age and Health Risk for Severe COVID-19: ≥ 18 and < 65 Years and at Risk

| | Placebo (N=2118) | mRNA-1273 (N=2155) |
|---|-------------------------|-----------------------|
| Number of Subjects with COVID-19, n (%) | 35 (1.7) | 2 (<0.1) |
| Number of Subjects Censored, n (%) | 2083 (98.3) | 2153 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.944 (0.769, 0.987) |
| Person-Years [2] | 494.9 | 506.7 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 70.716 (49.257, 98.349) | 3.947 (0.478, 14.257) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.944 (0.783, 0.993) |

Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.3.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19
Per-Protocol Set

Age and Health Risk for Severe COVID-19: >=65 Years

| | Placebo (N=3552) | mRNA-1273 (N=3583) |
|---|-------------------------|-----------------------|
| Number of Subjects with COVID-19, n (%) | 29 (0.8) | 4 (0.1) |
| Number of Subjects Censored, n (%) | 3523 (99.2) | 3579 (99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.864 (0.614, 0.952) |
| Person-Years [2] | 859.8 | 870.5 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 33.728 (22.588, 48.439) | 4.595 (1.252, 11.766) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.864 (0.612, 0.965) |

Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.4.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Sex
Per-Protocol Set

Sex: Male

| | Placebo (N=7462) | mRNA-1273 (N=7366) |
|---|-------------------------|-----------------------|
| Number of Subjects with COVID-19, n (%) | 87 (1.2) | 4 (<0.1) |
| Number of Subjects Censored, n (%) | 7375 (98.8) | 7362 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.954 (0.874, 0.983) |
| Person-Years [2] | 1715.0 | 1700.8 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 50.730 (40.632, 62.575) | 2.352 (0.641, 6.021) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.954 (0.877, 0.988) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.4.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Sex
Per-Protocol Set

Sex: Female

| | Placebo (N=6611) | mRNA-1273 (N=6768) |
|---|-------------------------|-----------------------|
| Number of Subjects with COVID-19, n (%) | 98 (1.5) | 7 (0.1) |
| Number of Subjects Censored, n (%) | 6513 (98.5) | 6761 (99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.931 (0.852, 0.968) |
| Person-Years [2] | 1558.8 | 1604.1 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 62.870 (51.041, 76.618) | 4.364 (1.754, 8.991) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.931 (0.852, 0.973) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Race
Per-Protocol Set

Race: White

| | Placebo (N=11174) | mRNA-1273 (N=11253) |
|---|-------------------------|------------------------|
| Number of Subjects with COVID-19, n (%) | 166 (1.5) | 11 (<0.1) |
| Number of Subjects Censored, n (%) | 11008 (98.5) | 11242 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.935 (0.880, 0.965) |
| Person-Years [2] | 2694.5 | 2728.1 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 61.606 (52.591, 71.724) | 4.032 (2.013, 7.215) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.935 (0.880, 0.968) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Race
Per-Protocol Set

Race: Black or African American

| | Placebo (N=1349) | mRNA-1273 (N=1385) |
|---|------------------------|-----------------------|
| Number of Subjects with COVID-19, n (%) | 6 (0.4) | 0 |
| Number of Subjects Censored, n (%) | 1343 (99.6) | 1385 (100) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 1.000 (NE, 1.000) |
| Person-Years [2] | 269.3 | 275.3 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 22.283 (8.177, 48.500) | 0.000 (NE, 13.402) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 1.000 (0.169, NE) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Race
Per-Protocol Set

Race: Asian

| | Placebo (N=689) | mRNA-1273 (N=620) |
|---|-------------------------|----------------------|
| Number of Subjects with COVID-19, n (%) | 5 (0.7) | 0 |
| Number of Subjects Censored, n (%) | 684 (99.3) | 620 (100) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 1.000 (NE, 1.000) |
| Person-Years [2] | 140.5 | 126.4 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 35.599 (11.559, 83.076) | 0.000 (NE, 29.176) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 1.000 (-0.212, NE) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.5.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Race
Per-Protocol Set

Race: American Indian or Alaska Native

| | Placebo (N=111) | mRNA-1273 (N=108) |
|---|-------------------------|----------------------|
| Number of Subjects with COVID-19, n (%) | 1 (0.9) | 0 |
| Number of Subjects Censored, n (%) | 110 (99.1) | 108 (100) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 1.000 (NE, 1.000) |
| Person-Years [2] | 22.3 | 22.2 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 44.788 (1.134, 249.545) | 0.000 (NE, 166.075) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 1.000 (-38.202, NE) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Race
Per-Protocol Set

Race: Native Hawaiian or Other Pacific Islander

| | Placebo (N=31) | mRNA-1273 (N=35) |
|---|---------------------|---------------------|
| Number of Subjects with COVID-19, n (%) | 0 | 0 |
| Number of Subjects Censored, n (%) | 31 (100) | 35 (100) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | NE (NE, NE) |
| Person-Years [2] | 6.9 | 7.7 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 0.000 (NE, 537.440) | 0.000 (NE, 481.545) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | NE (NE, NE) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Race
Per-Protocol Set

Race: Other

| | Placebo (N=295) | mRNA-1273 (N=299) |
|---|-------------------------|----------------------|
| Number of Subjects with COVID-19, n (%) | 2 (0.7) | 0 |
| Number of Subjects Censored, n (%) | 293 (99.3) | 299 (100) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 1.000 (NE, 1.000) |
| Person-Years [2] | 55.2 | 58.4 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 36.221 (4.387, 130.842) | 0.000 (NE, 63.215) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 1.000 (-4.038, NE) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Race
Per-Protocol Set

Race: Multiple

| | Placebo (N=307) | mRNA-1273 (N=295) |
|---|-------------------------|----------------------|
| Number of Subjects with COVID-19, n (%) | 3 (1.0) | 0 |
| Number of Subjects Censored, n (%) | 304 (99.0) | 295 (100) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 1.000 (NE, 1.000) |
| Person-Years [2] | 61.9 | 60.2 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 48.476 (9.997, 141.667) | 0.000 (NE, 61.294) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 1.000 (-1.488, NE) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Race
Per-Protocol Set

Race: Not Reported

| | Placebo (N=64) | mRNA-1273 (N=86) |
|---|-------------------------|---------------------|
| Number of Subjects with COVID-19, n (%) | 1 (1.6) | 0 |
| Number of Subjects Censored, n (%) | 63 (98.4) | 86 (100) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 1.000 (NE, 1.000) |
| Person-Years [2] | 14.1 | 17.5 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 71.060 (1.799, 395.923) | 0.000 (NE, 211.252) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 1.000 (-30.430, NE) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Race
Per-Protocol Set

Race: Unknown

| | Placebo (N=53) | mRNA-1273 (N=53) |
|---|--------------------------|---------------------|
| Number of Subjects with COVID-19, n (%) | 1 (1.9) | 0 |
| Number of Subjects Censored, n (%) | 52 (98.1) | 53 (100) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 1.000 (NE, 1.000) |
| Person-Years [2] | 9.1 | 9.3 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 109.487 (2.772, 610.025) | 0.000 (NE, 397.218) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 1.000 (-37.356, NE) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.6.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Ethnicity
Per-Protocol Set

Ethnicity: Hispanic or Latino

| | Placebo (N=2780) | mRNA-1273 (N=2789) |
|---|-------------------------|-----------------------|
| Number of Subjects with COVID-19, n (%) | 28 (1.0) | 1 (<0.1) |
| Number of Subjects Censored, n (%) | 2752 (99.0) | 2788 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.965 (0.744, 0.995) |
| Person-Years [2] | 563.8 | 568.8 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 49.662 (33.000, 71.775) | 1.758 (0.045, 9.795) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.965 (0.786, 0.999) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.6.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Ethnicity
Per-Protocol Set

Ethnicity: Not Hispanic or Latino

| | Placebo (N=11165) | mRNA-1273 (N=11212) |
|---|-------------------------|------------------------|
| Number of Subjects with COVID-19, n (%) | 156 (1.4) | 10 (<0.1) |
| Number of Subjects Censored, n (%) | 11009 (98.6) | 11202 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.937 (0.881, 0.967) |
| Person-Years [2] | 2679.9 | 2703.6 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 58.211 (49.435, 68.096) | 3.699 (1.774, 6.802) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.936 (0.880, 0.970) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.6.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Ethnicity
Per-Protocol Set

Ethnicity: Not Reported

| | Placebo (N=76) | mRNA-1273 (N=97) |
|---|---------------------|---------------------|
| Number of Subjects with COVID-19, n (%) | 0 | 0 |
| Number of Subjects Censored, n (%) | 76 (100) | 97 (100) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | NE (NE, NE) |
| Person-Years [2] | 19.1 | 24.6 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 0.000 (NE, 193.004) | 0.000 (NE, 150.157) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | NE (NE, NE) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.6.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Ethnicity
Per-Protocol Set

Ethnicity: Unknown

| | Placebo (N=52) | mRNA-1273 (N=36) |
|---|-------------------------|---------------------|
| Number of Subjects with COVID-19, n (%) | 1 (1.9) | 0 |
| Number of Subjects Censored, n (%) | 51 (98.1) | 36 (100) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 1.000 (NE, 1.000) |
| Person-Years [2] | 10.9 | 7.9 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 91.541 (2.318, 510.036) | 0.000 (NE, 465.250) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 1.000 (-52.733, NE) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.7.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: Yes

| | Placebo (N=3167) | mRNA-1273 (N=3206) |
|---|-------------------------|-----------------------|
| Number of Subjects with COVID-19, n (%) | 43 (1.4) | 4 (0.1) |
| Number of Subjects Censored, n (%) | 3124 (98.6) | 3202 (99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.909 (0.747, 0.967) |
| Person-Years [2] | 751.7 | 765.3 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 57.202 (41.398, 77.051) | 5.227 (1.424, 13.383) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.909 (0.749, 0.976) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.7.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: No

| | Placebo (N=10906) | mRNA-1273 (N=10928) |
|---|-------------------------|------------------------|
| Number of Subjects with COVID-19, n (%) | 142 (1.3) | 7 (<0.1) |
| Number of Subjects Censored, n (%) | 10764 (98.7) | 10921 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.951 (0.896, 0.977) |
| Person-Years [2] | 2522.0 | 2539.7 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 56.304 (47.424, 66.363) | 2.756 (1.108, 5.679) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.951 (0.896, 0.981) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.7.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: Chronic Lung Disease

| | Placebo (N=688) | mRNA-1273 (N=673) |
|---|--------------------------|-----------------------|
| Number of Subjects with COVID-19, n (%) | 9 (1.3) | 1 (0.1) |
| Number of Subjects Censored, n (%) | 679 (98.7) | 672 (99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.889 (0.125, 0.986) |
| Person-Years [2] | 169.2 | 167.1 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 53.181 (24.318, 100.955) | 5.984 (0.152, 33.342) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.887 (0.188, 0.997) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.7.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: Significant Cardiac Disease

| | Placebo (N=694) | mRNA-1273 (N=711) |
|---|-------------------------|-----------------------|
| Number of Subjects with COVID-19, n (%) | 6 (0.9) | 1 (0.1) |
| Number of Subjects Censored, n (%) | 688 (99.1) | 710 (99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.833 (-0.384, 0.980) |
| Person-Years [2] | 170.3 | 172.8 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 35.234 (12.930, 76.690) | 5.786 (0.146, 32.238) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.836 (-0.354, 0.996) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.7.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: Severe Obesity

| | Placebo (N=936) | mRNA-1273 (N=956) |
|---|--------------------------|-----------------------|
| Number of Subjects with COVID-19, n (%) | 19 (2.0) | 2 (0.2) |
| Number of Subjects Censored, n (%) | 917 (98.0) | 954 (99.8) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.899 (0.568, 0.977) |
| Person-Years [2] | 220.6 | 229.0 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 86.124 (51.852, 134.493) | 8.734 (1.058, 31.550) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.899 (0.580, 0.989) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.7.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: Diabetes

| | Placebo (N=1345) | mRNA-1273 (N=1364) |
|---|-------------------------|-----------------------|
| Number of Subjects with COVID-19, n (%) | 16 (1.2) | 1 (<0.1) |
| Number of Subjects Censored, n (%) | 1329 (98.8) | 1363 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.939 (0.538, 0.992) |
| Person-Years [2] | 315.8 | 321.2 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 50.666 (28.960, 82.279) | 3.113 (0.079, 17.345) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.939 (0.605, 0.999) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.7.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: Liver Disease

| | Placebo (N=90) | mRNA-1273 (N=95) |
|---|---------------------|---------------------|
| Number of Subjects with COVID-19, n (%) | 0 | 0 |
| Number of Subjects Censored, n (%) | 90 (100) | 95 (100) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | NE (NE, NE) |
| Person-Years [2] | 21.0 | 21.6 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 0.000 (NE, 175.301) | 0.000 (NE, 170.725) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | NE (NE, NE) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.7.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: Human Immunodeficiency Virus Infection

| | Placebo (N=77) | mRNA-1273 (N=82) |
|---|-------------------------|---------------------|
| Number of Subjects with COVID-19, n (%) | 1 (1.3) | 0 |
| Number of Subjects Censored, n (%) | 76 (98.7) | 82 (100) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 1.000 (NE, 1.000) |
| Person-Years [2] | 14.0 | 15.7 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 71.394 (1.808, 397.780) | 0.000 (NE, 235.677) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 1.000 (-33.900, NE) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.10.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race and Ethnicity Group (White, Communities of Color)
Per-Protocol Set

Race and Ethnicity Group: White

| | Placebo (N=8916) | mRNA-1273 (N=9023) |
|---|-------------------------|-----------------------|
| Number of Subjects with COVID-19, n (%) | 144 (1.6) | 10 (0.1) |
| Number of Subjects Censored, n (%) | 8772 (98.4) | 9013 (99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.932 (0.871, 0.964) |
| Person-Years [2] | 2228.8 | 2265.9 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 64.608 (54.487, 76.064) | 4.413 (2.116, 8.116) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.932 (0.871, 0.968) |

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.

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.10.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race and Ethnicity Group (White, Communities of Color)
Per-Protocol Set

Race and Ethnicity Group: Communities of Color

| | Placebo (N=5132) | mRNA-1273 (N=5088) |
|---|-------------------------|-----------------------|
| Number of Subjects with COVID-19, n (%) | 41 (0.8) | 1 (<0.1) |
| Number of Subjects Censored, n (%) | 5091 (99.2) | 5087 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.975 (0.822, 0.997) |
| Person-Years [2] | 1039.5 | 1033.8 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 39.443 (28.305, 53.509) | 0.967 (0.024, 5.390) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.975 (0.855, 0.999) |

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.

- [1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.11.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19 (≥ 18 and < 65 Years and Not at Risk, ≥ 18 and < 65 Years and at Risk, ≥ 65 Years and Not at Risk, ≥ 65 Years and at Risk)
Per-Protocol Set

Age and Health Risk for Severe COVID-19: ≥ 18 and < 65 Years and Not at Risk

| | Placebo (N=8403) | mRNA-1273 (N=8396) |
|---|-------------------------|-----------------------|
| Number of Subjects with COVID-19, n (%) | 121 (1.4) | 5 (<0.1) |
| Number of Subjects Censored, n (%) | 8282 (98.6) | 8391 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.959 (0.900, 0.983) |
| Person-Years [2] | 1919.0 | 1927.7 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 63.054 (52.321, 75.342) | 2.594 (0.842, 6.053) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.959 (0.901, 0.987) |

Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio}$ (mRNA-1273 vs. placebo), and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate}$ (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.11.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19 (≥ 18 and < 65 Years and Not at Risk, ≥ 18 and < 65 Years and at Risk, ≥ 65 Years and Not at Risk, ≥ 65 Years and at Risk)
Per-Protocol Set

Age and Health Risk for Severe COVID-19: ≥ 18 and < 65 Years and at Risk

| | Placebo (N=2118) | mRNA-1273 (N=2155) |
|---|-------------------------|-----------------------|
| Number of Subjects with COVID-19, n (%) | 35 (1.7) | 2 (<0.1) |
| Number of Subjects Censored, n (%) | 2083 (98.3) | 2153 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.944 (0.769, 0.987) |
| Person-Years [2] | 494.9 | 506.7 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 70.716 (49.257, 98.349) | 3.947 (0.478, 14.257) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.944 (0.783, 0.993) |

Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.11.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19 (≥ 18 and < 65 Years and Not at Risk, ≥ 18 and < 65 Years and at Risk, ≥ 65 Years and Not at Risk, ≥ 65 Years and at Risk)
Per-Protocol Set

Age and Health Risk for Severe COVID-19: ≥ 65 Years and Not at Risk

| | Placebo (N=2503) | mRNA-1273 (N=2532) |
|---|-------------------------|-----------------------|
| Number of Subjects with COVID-19, n (%) | 21 (0.8) | 2 (<0.1) |
| Number of Subjects Censored, n (%) | 2482 (99.2) | 2530 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.907 (0.602, 0.978) |
| Person-Years [2] | 603.0 | 612.0 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 34.823 (21.556, 53.231) | 3.268 (0.396, 11.806) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.906 (0.616, 0.989) |

Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio}$ (mRNA-1273 vs. placebo), and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate}$ (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.1.6.11.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19 (≥ 18 and < 65 Years and Not at Risk, ≥ 18 and < 65 Years and at Risk, ≥ 65 Years and Not at Risk, ≥ 65 Years and at Risk)
Per-Protocol Set

Age and Health Risk for Severe COVID-19: ≥ 65 Years and at Risk

| | Placebo (N=1049) | mRNA-1273 (N=1051) |
|---|-------------------------|-----------------------|
| Number of Subjects with COVID-19, n (%) | 8 (0.8) | 2 (0.2) |
| Number of Subjects Censored, n (%) | 1041 (99.2) | 1049 (99.8) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.752 (-0.169, 0.947) |
| Person-Years [2] | 256.8 | 258.5 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 31.155 (13.450, 61.387) | 7.737 (0.937, 27.948) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.752 (-0.244, 0.974) |

Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.2.1.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Starting 14 Days After Second Injection
Per-Protocol Set

| | Placebo (N=14073) | mRNA-1273 (N=14134) |
|---|-------------------------|------------------------|
| Number of Subjects with COVID-19, n (%) | 202 (1.4) | 11 (<0.1) |
| Number of Subjects Censored, n (%) | 13871 (98.6) | 14123 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.947 (0.902, 0.971) |
| Person-Years [2] | 3271.1 | 3304.8 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 61.754 (53.531, 70.882) | 3.329 (1.662, 5.956) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.946 (0.901, 0.974) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.2.3.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Starting 14 Days After First Injection
Per-Protocol Set

| | Placebo (N=14073) | mRNA-1273 (N=14134) |
|---|-------------------------|------------------------|
| Number of Subjects with COVID-19, n (%) | 225 (1.6) | 11 (<0.1) |
| Number of Subjects Censored, n (%) | 13848 (98.4) | 14123 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.952 (0.912, 0.974) |
| Person-Years [2] | 3271.1 | 3304.8 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 68.785 (60.090, 78.384) | 3.329 (1.662, 5.956) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.952 (0.912, 0.976) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.2.5.1
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Starting After Randomization
Per-Protocol Set

| | Placebo (N=14073) | mRNA-1273 (N=14134) |
|---|-------------------------|------------------------|
| Number of Subjects with COVID-19, n (%) | 225 (1.6) | 12 (<0.1) |
| Number of Subjects Censored, n (%) | 13848 (98.4) | 14122 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.948 (0.906, 0.971) |
| Person-Years [2] | 3271.1 | 3304.8 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 68.785 (60.090, 78.384) | 3.631 (1.876, 6.343) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.947 (0.906, 0.973) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.2.5.2
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Starting After Randomization
mITT Set

| | Placebo (N=14598) | mRNA-1273 (N=14550) |
|---|-------------------------|------------------------|
| Number of Subjects with COVID-19, n (%) | 269 (1.8) | 19 (0.1) |
| Number of Subjects Censored, n (%) | 14329 (98.2) | 14531 (99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.930 (0.889, 0.956) |
| Person-Years [2] | 3373.2 | 3388.8 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 79.746 (70.500, 89.868) | 5.607 (3.376, 8.756) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.930 (0.888, 0.958) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.1.1.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection
Per-Protocol Set

| | Placebo (N=14073) | mRNA-1273 (N=14134) |
|---|-----------------------|------------------------|
| Number of Subjects with Severe COVID-19, n (%) | 30 (0.2) | 0 |
| Number of Subjects Censored, n (%) | 14043 (99.8) | 14134 (100) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 1.000 (NE, 1.000) |
| Person-Years [2] | 3282.9 | 3305.4 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 9.138 (6.166, 13.046) | 0.000 (NE, 1.116) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 1.000 (0.870, NE) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
- [2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.1.1.2
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19 Based on Adjudication Committee Assessments Starting
14 Days After Second Injection
mITT Set

| | Placebo (N=14598) | mRNA-1273 (N=14550) |
|---|-----------------------|------------------------|
| Number of Subjects with Severe COVID-19, n (%) | 30 (0.2) | 0 |
| Number of Subjects Censored, n (%) | 14568 (99.8) | 14550 (100) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 1.000 (NE, 1.000) |
| Person-Years [2] | 3392.0 | 3390.8 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 8.844 (5.967, 12.626) | 0.000 (NE, 1.088) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 1.000 (0.869, NE) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
- [2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.1.6.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19 Based on Adjudication Committee Assessments
Starting 14 Days After Second Injection by Age Group (≥ 18 and < 65 Years, ≥ 65 Years)

Per-Protocol Set

Age Group: ≥ 18 and < 65 Years

| | Placebo (N=10521) | mRNA-1273 (N=10551) |
|---|-----------------------|------------------------|
| Number of Subjects with Severe COVID-19, n (%) | 20 (0.2) | 0 |
| Number of Subjects Censored, n (%) | 10501 (99.8) | 10551 (100) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 1.000 (NE, 1.000) |
| Person-Years [2] | 2421.7 | 2434.9 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 8.259 (5.045, 12.755) | 0.000 (NE, 1.515) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 1.000 (0.799, NE) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.1.6.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19 Based on Adjudication Committee Assessments
Starting 14 Days After Second Injection by Age Group (≥ 18 and < 65 Years, ≥ 65 Years)
Per-Protocol Set

Age Group: ≥ 65 Years

| | Placebo (N=3552) | mRNA-1273 (N=3583) |
|---|------------------------|-----------------------|
| Number of Subjects with Severe COVID-19, n (%) | 10 (0.3) | 0 |
| Number of Subjects Censored, n (%) | 3542 (99.7) | 3583 (100) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 1.000 (NE, 1.000) |
| Person-Years [2] | 861.1 | 870.6 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 11.613 (5.569, 21.356) | 0.000 (NE, 4.237) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 1.000 (0.559, NE) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.1.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19 Starting 14 Days After Second Injection
Per-Protocol Set

| | Placebo (N=14073) | mRNA-1273 (N=14134) |
|---|------------------------|------------------------|
| Number of Subjects with Severe COVID-19, n (%) | 38 (0.3) | 0 |
| Number of Subjects Censored, n (%) | 14035 (99.7) | 14134 (100) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 1.000 (NE, 1.000) |
| Person-Years [2] | 3282.5 | 3305.4 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 11.577 (8.192, 15.890) | 0.000 (NE, 1.116) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 1.000 (0.899, NE) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
- [2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.5.1
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19 Starting After Randomization
Per-Protocol Set

| | Placebo (N=14073) | mRNA-1273 (N=14134) |
|---|------------------------|------------------------|
| Number of Subjects with Severe COVID-19, n (%) | 39 (0.3) | 0 |
| Number of Subjects Censored, n (%) | 14034 (99.7) | 14134 (100) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 1.000 (NE, 1.000) |
| Person-Years [2] | 3282.5 | 3305.4 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 11.881 (8.449, 16.242) | 0.000 (NE, 1.116) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 1.000 (0.901, NE) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
- [2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.4.1.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Secondary Definition of COVID-19 Starting 14 Days After Second Injection
Per-Protocol Set

| | Placebo (N=14073) | mRNA-1273 (N=14134) |
|--|-------------------------|------------------------|
| Number of Subjects with Secondary Definition of COVID-19, n (%) | 221 (1.6) | 11 (<0.1) |
| Number of Subjects Censored, n (%) | 13852 (98.4) | 14123 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.951 (0.911, 0.973) |
| Person-Years [2] | 3269.8 | 3304.8 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 67.589 (58.971, 77.112) | 3.329 (1.662, 5.956) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.951 (0.910, 0.976) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
- [2] Person-years is defined as the total years from randomization date to the date of secondary definition of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.7.1.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days
After Second Injection Regardless of Prior SARS-CoV-2 Infection
Full Analysis Set

| | Placebo (N=15170) | mRNA-1273 (N=15181) |
|---|-------------------------|------------------------|
| Number of Subjects with COVID-19, n (%) | 187 (1.2) | 12 (<0.1) |
| Number of Subjects Censored, n (%) | 14983 (98.8) | 15169 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.936 (0.886, 0.965) |
| Person-Years [2] | 3507.9 | 3525.1 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 53.309 (45.942, 61.521) | 3.404 (1.759, 5.946) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.936 (0.886, 0.968) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.7.1.6.10

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection Regardless of Prior SARS-CoV-2 Infection by Baseline SARS-CoV-2 Status
Full Analysis Set

Baseline SARS-CoV-2 Status: Negative

| | Placebo (N=14598) | mRNA-1273 (N=14550) |
|---|-------------------------|------------------------|
| Number of Subjects with COVID-19, n (%) | 185 (1.3) | 12 (<0.1) |
| Number of Subjects Censored, n (%) | 14413 (98.7) | 14538 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.936 (0.885, 0.964) |
| Person-Years [2] | 3382.9 | 3390.1 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 54.688 (47.091, 63.161) | 3.540 (1.829, 6.183) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.935 (0.884, 0.967) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.7.1.6.10

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection Regardless of Prior SARS-CoV-2 Infection by Baseline SARS-CoV-2 Status
Full Analysis Set

Baseline SARS-CoV-2 Status: Positive

| | Placebo (N=337) | mRNA-1273 (N=343) |
|---|------------------------|----------------------|
| Number of Subjects with COVID-19, n (%) | 1 (0.3) | 0 |
| Number of Subjects Censored, n (%) | 336 (99.7) | 343 (100) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 1.000 (NE, 1.000) |
| Person-Years [2] | 71.9 | 71.4 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 13.915 (0.352, 77.528) | 0.000 (NE, 51.653) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 1.000 (-38.245, NE) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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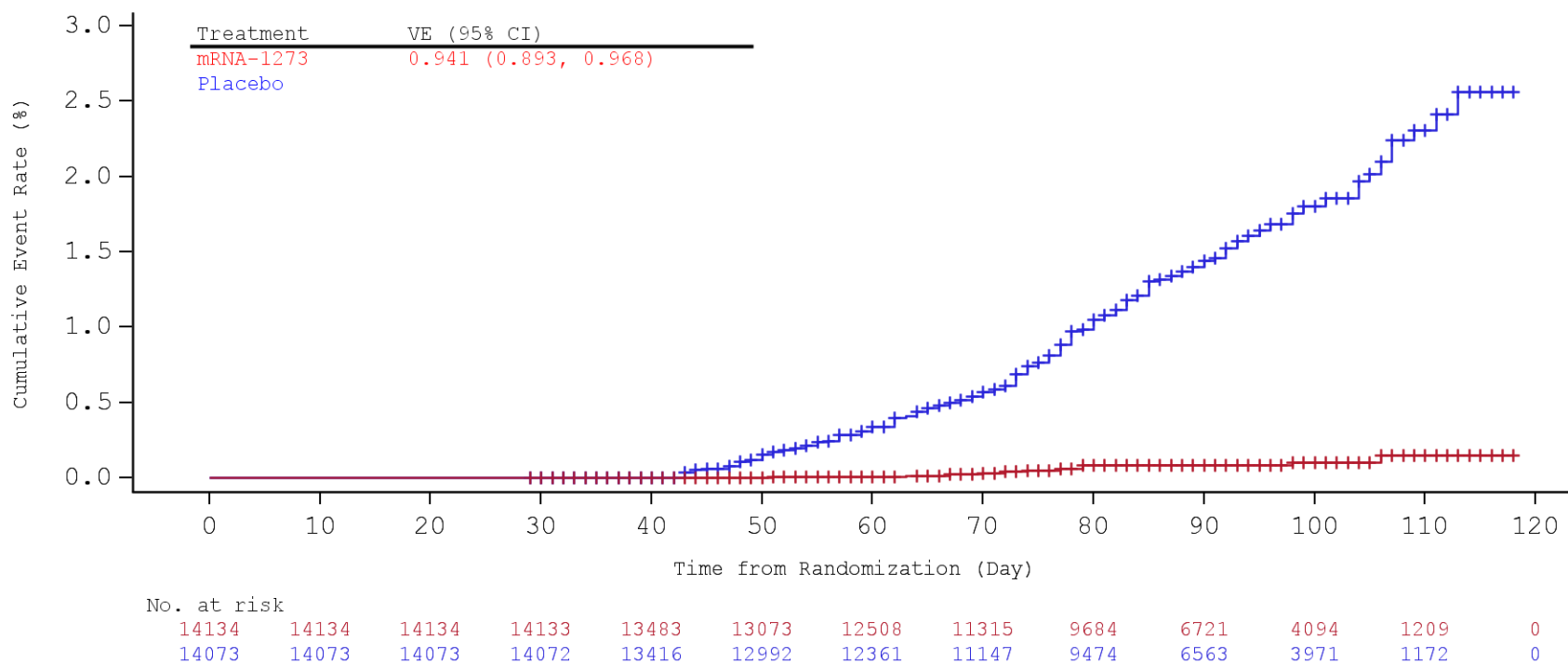
Table 14.2.2.7.2.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Starting 14 Days After Second Injection Regardless of Prior SARS-CoV-2 Infection
Full Analysis Set

| | Placebo (N=15170) | mRNA-1273 (N=15181) |
|---|-------------------------|------------------------|
| Number of Subjects with COVID-19, n (%) | 207 (1.4) | 12 (<0.1) |
| Number of Subjects Censored, n (%) | 14963 (98.6) | 15169 (>99.9) |
| Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] | | 0.943 (0.898, 0.968) |
| Person-Years [2] | 3497.1 | 3522.5 |
| Incidence Rate per 1,000 Person-Years (95% CI) [3] | 59.191 (51.402, 67.827) | 3.407 (1.760, 5.951) |
| Vaccine Efficacy Based on Incidence Rate (95% CI) [4] | | 0.942 (0.897, 0.971) |

- [1] Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
- [3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
- [4] VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Figure 14.2.2.1.1.1.1
Kaplan-Meier Estimates of Time to First Occurrence of COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set



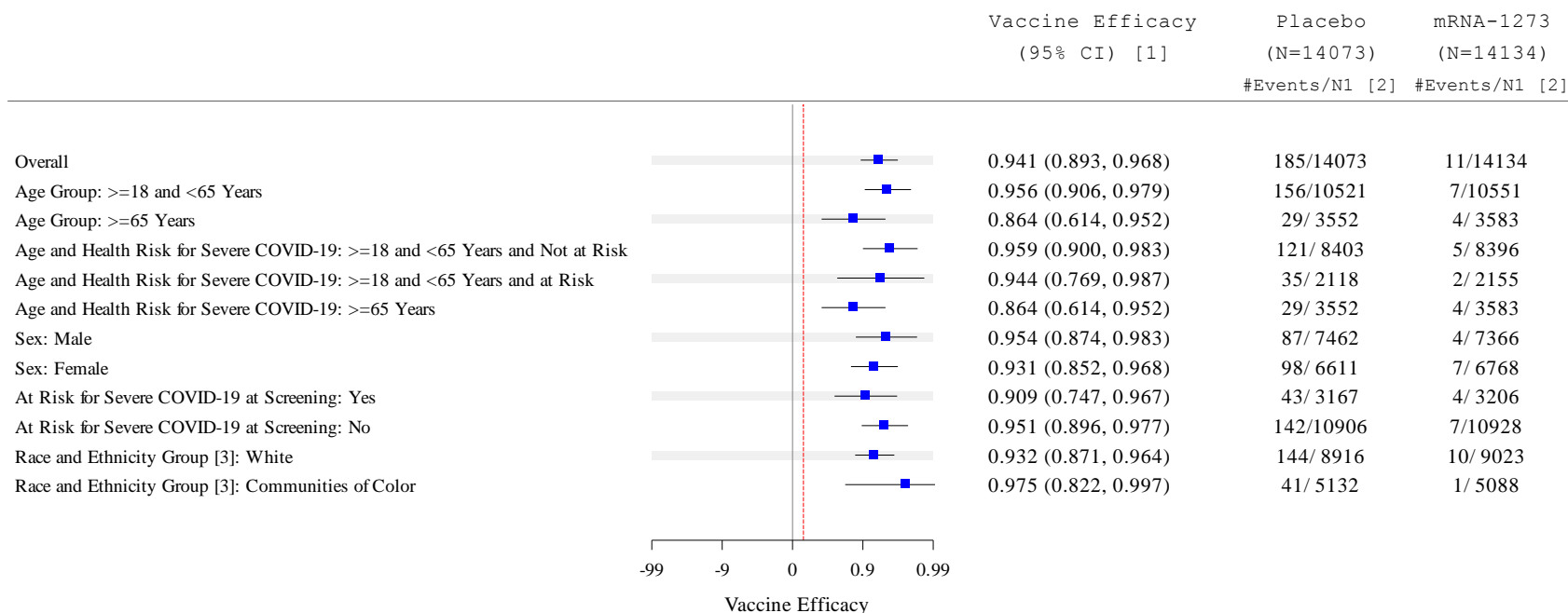
Source table: Table 14.2.2.1.1.1.1.

Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

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Figure 14.2.2.1.1.2.3

Forest Plot of Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set



Source table: Table 14.2.2.1.1.1.1, Table 14.2.2.1.1.6.1.1, Table 14.2.2.1.1.6.3.1, Table 14.2.2.1.1.6.4.1, Table 14.2.2.1.1.6.7.1, Table 14.2.2.1.1.6.10.1.

Reference line indicates vaccine efficacy of 0.3.

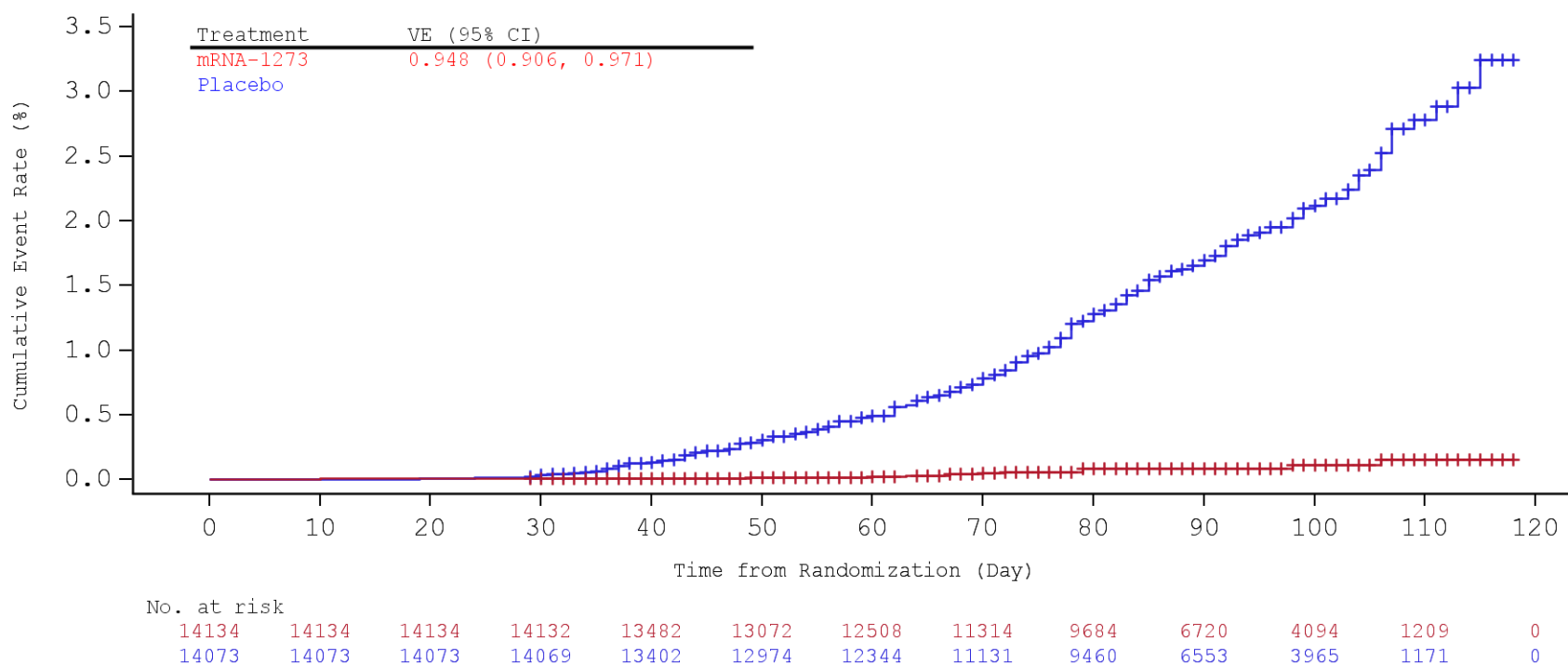
[1] Vaccine efficacy, defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Based on the number of subjects in each subgroup.

[3] 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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Figure 14.2.2.1.2.1.3
Kaplan-Meier Estimates of Time to First Occurrence of COVID-19 Starting After Randomization
Per-Protocol Set

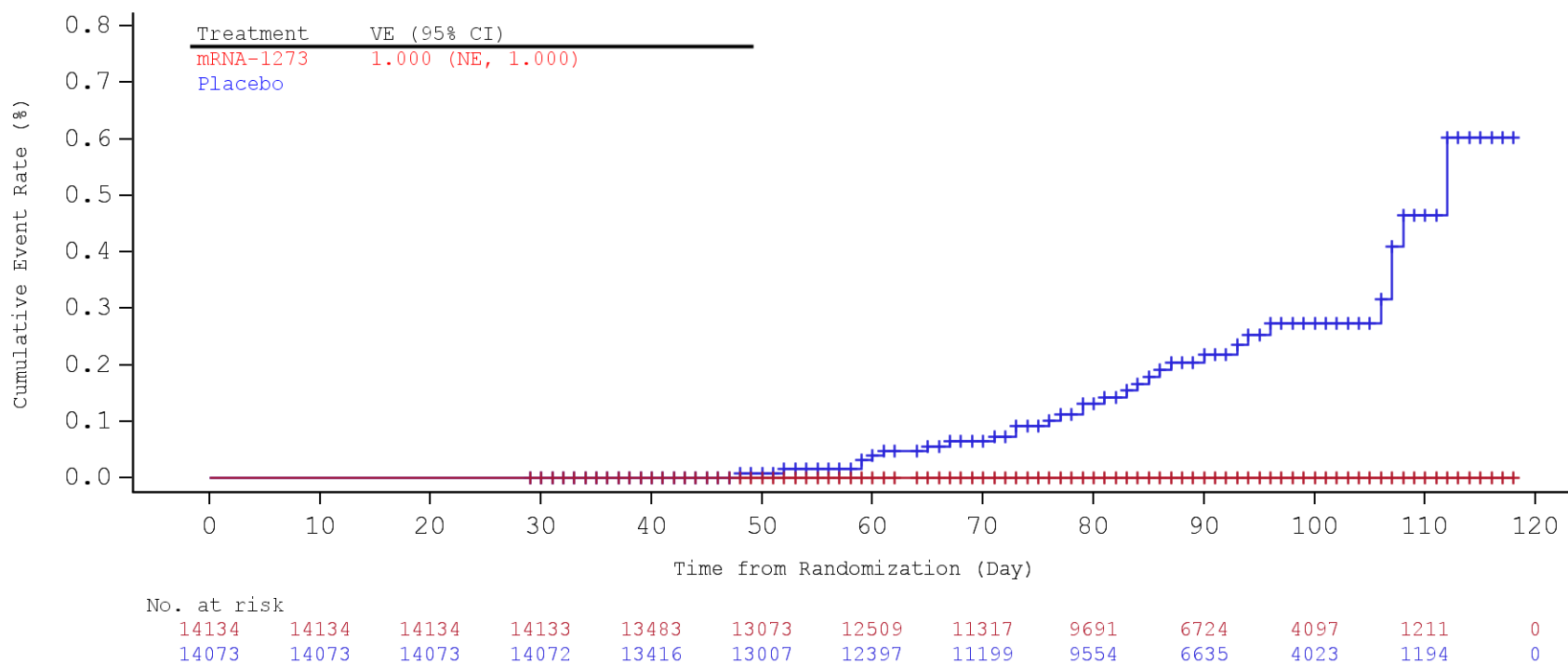


Source table: Table 14.2.2.1.2.5.1.

Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

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Figure 14.2.2.2.1.1.1
Kaplan-Meier Estimates of Time to First Occurrence of Severe COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set

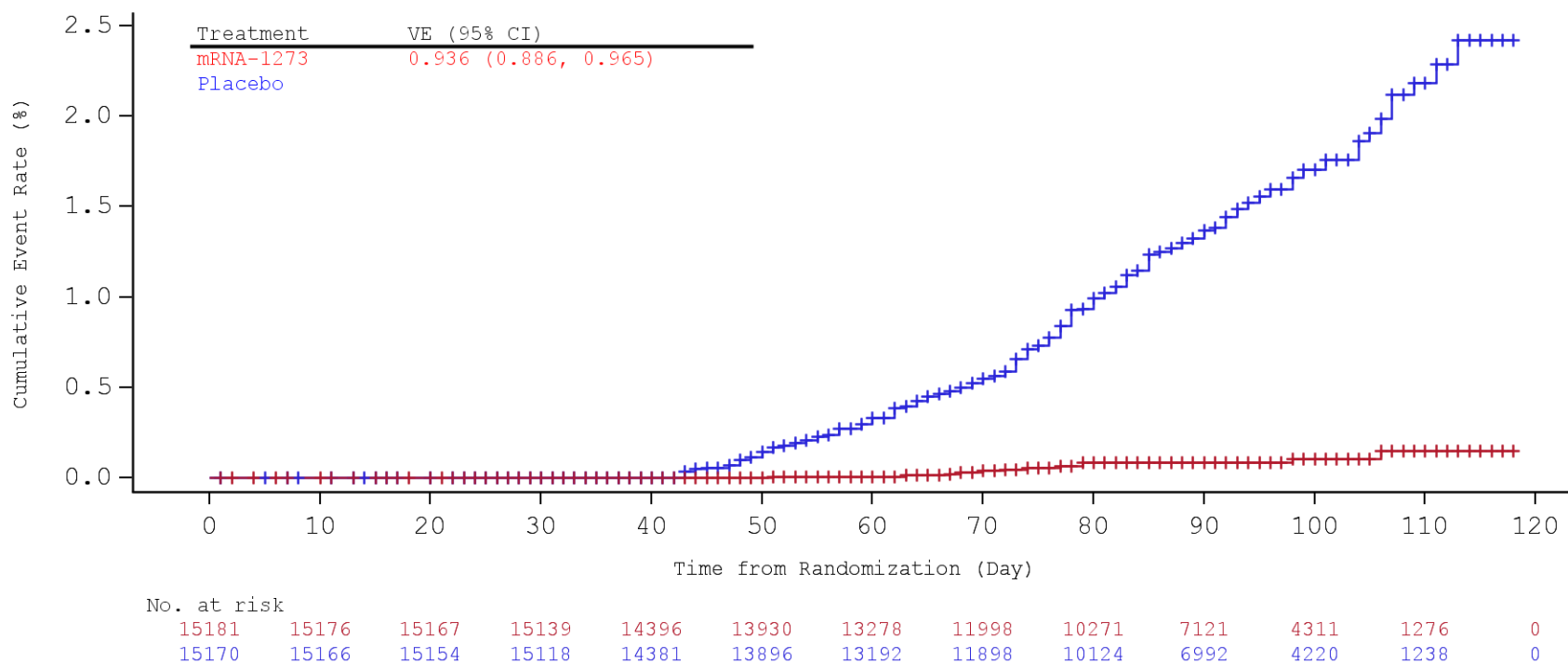


Source table: Table 14.2.2.2.1.1.1.

Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

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Figure 14.2.2.7.1.1.1
Kaplan-Meier Estimates of Time to First Occurrence of COVID-19 Based on Adjudication Committee Assessments Starting 14 Days
After Second Injection Regardless of Prior SARS-CoV-2 Infection
Full Analysis Set



Source table: Table 14.2.2.7.1.1.

Vaccine efficacy (VE), defined as $1 - \text{hazard ratio (mRNA-1273 vs. placebo)}$, and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

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