

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

	Placebo (N=13883)	mRNA-1273 (N=13934)
COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection		
Number of Events	90	5
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] p-value [2]		0.945 (0.865, 0.978) <.0001
COVID-19 Starting 14 Days After Second Injection		
Number of Events	107	6
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.945 (0.874, 0.976)
Severe COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection		
Number of Events	11	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	15	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	121	6
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.951 (0.889, 0.978)

[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=13883)	mRNA-1273 (N=13934)
Death Caused by COVID-19 Starting 14 Days After Second Injection		
Number of Events	0	0
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		NE (NE, NE)
COVID-19 Starting 14 Days After First Injection		
Number of Events	128	6
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.954 (0.895, 0.980)
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	92/15170	6/15180
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.935 (0.852, 0.972)
COVID-19 Starting 14 Days After Second Injection Regardless of Prior SARS-CoV-2 Infection, n/N [3]		
Number of Events	111/15170	7/15180
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.938 (0.866, 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] 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=13883)	mRNA-1273 (N=13934)
Number of Subjects with COVID-19, n (%)	90 (0.6)	5 (<0.1)
Number of Subjects Censored, n (%)	13793 (99.4)	13929 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1] p-value [2]		0.945 (0.865, 0.978) <.0001
Person-Years [3]	2697.5	2716.9
Incidence Rate per 1,000 Person-Years (95% CI) [4]	33.365 (26.829, 41.011)	1.840 (0.598, 4.295)
Vaccine Efficacy Based on Incidence Rate (95% CI) [5]		0.945 (0.866, 0.983)

- [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 or last date of study participation, 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=14370)	mRNA-1273 (N=14312)
Number of Subjects with COVID-19, n (%)	90 (0.6)	6 (<0.1)
Number of Subjects Censored, n (%)	14280 (99.4)	14306 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.934 (0.848, 0.971)
Person-Years [2]	2786.5	2785.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	32.298 (25.972, 39.700)	2.154 (0.790, 4.688)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.933 (0.849, 0.976)

- [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.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19 or last date of study participation, 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 14.2.2.1.1.6.1.1

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=10384)	mRNA-1273 (N=10407)
Number of Subjects with COVID-19, n (%)	75 (0.7)	5 (<0.1)
Number of Subjects Censored, n (%)	10309 (99.3)	10402 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.934 (0.837, 0.973)
Person-Years [2]	1984.8	1996.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	37.788 (29.723, 47.368)	2.504 (0.813, 5.843)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.934 (0.838, 0.979)

- [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 or last date of study participation, 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=3499)	mRNA-1273 (N=3527)
Number of Subjects with COVID-19, n (%)	15 (0.4)	0
Number of Subjects Censored, n (%)	3484 (99.6)	3527 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	712.7	720.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	21.046 (11.780, 34.713)	0.000 (NE, 5.123)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.724, 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 or last date of study participation, 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=8323)	mRNA-1273 (N=8309)
Number of Subjects with COVID-19, n (%)	57 (0.7)	4 (<0.1)
Number of Subjects Censored, n (%)	8266 (99.3)	8305 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.930 (0.808, 0.975)
Person-Years [2]	1581.8	1585.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	36.034 (27.292, 46.687)	2.524 (0.688, 6.462)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.930 (0.811, 0.982)

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 or last date of study participation, 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=2061)	mRNA-1273 (N=2098)
Number of Subjects with COVID-19, n (%)	18 (0.9)	1 (<0.1)
Number of Subjects Censored, n (%)	2043 (99.1)	2097 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.946 (0.594, 0.993)
Person-Years [2]	402.9	411.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	44.673 (26.476, 70.602)	2.428 (0.061, 13.528)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.946 (0.656, 0.999)

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 or last date of study participation, 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=3499)	mRNA-1273 (N=3527)
Number of Subjects with COVID-19, n (%)	15 (0.4)	0
Number of Subjects Censored, n (%)	3484 (99.6)	3527 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	712.7	720.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	21.046 (11.780, 34.713)	0.000 (NE, 5.123)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.724, NE)

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 - 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 or last date of study participation, 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 14.2.2.1.1.6.4.1
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=7369)	mRNA-1273 (N=7273)
Number of Subjects with COVID-19, n (%)	45 (0.6)	2 (<0.1)
Number of Subjects Censored, n (%)	7324 (99.4)	7271 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.955 (0.815, 0.989)
Person-Years [2]	1411.4	1395.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	31.883 (23.255, 42.661)	1.433 (0.174, 5.176)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.955 (0.828, 0.995)

- [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 or last date of study participation, 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 14.2.2.1.1.6.4.1
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=6514)	mRNA-1273 (N=6661)
Number of Subjects with COVID-19, n (%)	45 (0.7)	3 (<0.1)
Number of Subjects Censored, n (%)	6469 (99.3)	6658 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.935 (0.792, 0.980)
Person-Years [2]	1286.0	1321.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	34.991 (25.523, 46.821)	2.271 (0.468, 6.637)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.935 (0.798, 0.987)

- [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 or last date of study participation, 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=3075)	mRNA-1273 (N=3116)
Number of Subjects with COVID-19, n (%)	24 (0.8)	1 (<0.1)
Number of Subjects Censored, n (%)	3051 (99.2)	3115 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.959 (0.697, 0.994)
Person-Years [2]	612.6	623.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	39.177 (25.102, 58.292)	1.604 (0.041, 8.935)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.959 (0.749, 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 or last date of study participation, 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=10808)	mRNA-1273 (N=10818)
Number of Subjects with COVID-19, n (%)	66 (0.6)	4 (<0.1)
Number of Subjects Censored, n (%)	10742 (99.4)	10814 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.940 (0.835, 0.978)
Person-Years [2]	2084.9	2093.3
Incidence Rate per 1,000 Person-Years (95% CI) [3]	31.657 (24.483, 40.275)	1.911 (0.521, 4.893)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.940 (0.838, 0.984)

- [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 or last date of study participation, 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 14.2.2.1.1.6.7.1

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=673)	mRNA-1273 (N=661)
Number of Subjects with COVID-19, n (%)	6 (0.9)	0
Number of Subjects Censored, n (%)	667 (99.1)	661 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	139.7	138.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	42.950 (15.762, 93.485)	0.000 (NE, 26.573)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.145, 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 or last date of study participation, 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=678)	mRNA-1273 (N=686)
Number of Subjects with COVID-19, n (%)	3 (0.4)	0
Number of Subjects Censored, n (%)	675 (99.6)	686 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	139.8	140.2
Incidence Rate per 1,000 Person-Years (95% CI) [3]	21.463 (4.426, 62.723)	0.000 (NE, 26.307)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-1.412, 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 or last date of study participation, 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=884)	mRNA-1273 (N=901)
Number of Subjects with COVID-19, n (%)	11 (1.2)	1 (0.1)
Number of Subjects Censored, n (%)	873 (98.8)	900 (99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.912 (0.320, 0.989)
Person-Years [2]	175.0	181.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	62.851 (31.375, 112.458)	5.524 (0.140, 30.776)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.912 (0.395, 0.998)

[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 or last date of study participation, 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=1309)	mRNA-1273 (N=1338)
Number of Subjects with COVID-19, n (%)	7 (0.5)	0
Number of Subjects Censored, n (%)	1302 (99.5)	1338 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	257.8	263.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	27.148 (10.915, 55.936)	0.000 (NE, 13.996)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.321, 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 or last date of study participation, 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=93)
Number of Subjects with COVID-19, n (%)	0	0
Number of Subjects Censored, n (%)	90 (100)	93 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		NE (NE, NE)
Person-Years [2]	17.4	17.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	0.000 (NE, 211.550)	0.000 (NE, 211.318)
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 or last date of study participation, 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=76)	mRNA-1273 (N=80)
Number of Subjects with COVID-19, n (%)	1 (1.3)	0
Number of Subjects Censored, n (%)	75 (98.7)	80 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	11.0	12.2
Incidence Rate per 1,000 Person-Years (95% CI) [3]	91.108 (2.307, 507.619)	0.000 (NE, 303.255)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-34.190, 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 or last date of study participation, 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=8755)	mRNA-1273 (N=8858)
Number of Subjects with COVID-19, n (%)	70 (0.8)	5 (<0.1)
Number of Subjects Censored, n (%)	8685 (99.2)	8853 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.930 (0.826, 0.972)
Person-Years [2]	1855.7	1881.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	37.721 (29.406, 47.659)	2.657 (0.863, 6.200)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.930 (0.828, 0.978)

White is defined as White and non-Hispanic, and Communities of Color includes all the others.

- [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 or last date of study participation, 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 14.2.2.1.1.6.10.1

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=5102)	mRNA-1273 (N=5054)
Number of Subjects with COVID-19, n (%)	20 (0.4)	0
Number of Subjects Censored, n (%)	5082 (99.6)	5054 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	837.1	830.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	23.892 (14.594, 36.899)	0.000 (NE, 4.440)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.796, NE)

White is defined as White and non-Hispanic, and Communities of Color includes all the others.

- [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 or last date of study participation, 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 14.2.2.1.2.1.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Starting 14 Days After Second Injection
Per-Protocol Set

	Placebo (N=13883)	mRNA-1273 (N=13934)
Number of Subjects with COVID-19, n (%)	107 (0.8)	6 (<0.1)
Number of Subjects Censored, n (%)	13776 (99.2)	13928 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.945 (0.874, 0.976)
Person-Years [2]	2695.6	2716.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	39.695 (32.531, 47.967)	2.209 (0.810, 4.807)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.944 (0.875, 0.980)

- [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 or last date of study participation, 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=13883)	mRNA-1273 (N=13934)
Number of Subjects with COVID-19, n (%)	128 (0.9)	6 (<0.1)
Number of Subjects Censored, n (%)	13755 (99.1)	13928 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.954 (0.895, 0.980)
Person-Years [2]	2695.6	2716.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	47.485 (39.616, 56.460)	2.209 (0.810, 4.807)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.953 (0.896, 0.983)

- [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 or last date of study participation, 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=13883)	mRNA-1273 (N=13934)
Number of Subjects with COVID-19, n (%)	128 (0.9)	7 (<0.1)
Number of Subjects Censored, n (%)	13755 (99.1)	13927 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.946 (0.884, 0.975)
Person-Years [2]	2695.6	2716.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	47.485 (39.616, 56.460)	2.577 (1.036, 5.309)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.946 (0.885, 0.979)

- [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 or last date of study participation, 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=14370)	mRNA-1273 (N=14312)
Number of Subjects with COVID-19, n (%)	166 (1.2)	14 (<0.1)
Number of Subjects Censored, n (%)	14204 (98.8)	14298 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.916 (0.855, 0.951)
Person-Years [2]	2779.5	2784.3
Incidence Rate per 1,000 Person-Years (95% CI) [3]	59.723 (50.983, 69.531)	5.028 (2.749, 8.436)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.916 (0.855, 0.955)

- [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 or last date of study participation, 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=13883)	mRNA-1273 (N=13934)
Number of Subjects with Severe COVID-19, n (%)	11 (<0.1)	0
Number of Subjects Censored, n (%)	13872 (>99.9)	13934 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	2701.2	2717.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	4.072 (2.033, 7.286)	0.000 (NE, 1.358)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.604, NE)

- [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.
- [2] Person-years is defined as the total years from randomization date to the date of severe COVID-19 or last date of study participation, 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 14.2.2.2.1.1.2
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=14370)	mRNA-1273 (N=14312)
Number of Subjects with Severe COVID-19, n (%)	11 (<0.1)	0
Number of Subjects Censored, n (%)	14359 (>99.9)	14312 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	2790.2	2785.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	3.942 (1.968, 7.054)	0.000 (NE, 1.324)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.601, NE)

- [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.
- [2] Person-years is defined as the total years from randomization date to the date of severe COVID-19 or last date of study participation, 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 14.2.2.2.1.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19 Starting 14 Days After Second Injection
Per-Protocol Set

	Placebo (N=13883)	mRNA-1273 (N=13934)
Number of Subjects with Severe COVID-19, n (%)	15 (0.1)	0
Number of Subjects Censored, n (%)	13868 (99.9)	13934 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	2701.0	2717.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	5.554 (3.108, 9.160)	0.000 (NE, 1.358)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.723, 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 or last date of study participation, 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 14.2.2.2.2.5.1
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19 Starting After Randomization
Per-Protocol Set

	Placebo (N=13883)	mRNA-1273 (N=13934)
Number of Subjects with Severe COVID-19, n (%)	16 (0.1)	0
Number of Subjects Censored, n (%)	13867 (99.9)	13934 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	2701.0	2717.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	5.924 (3.386, 9.620)	0.000 (NE, 1.358)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.742, 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 or last date of study participation, 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=13883)	mRNA-1273 (N=13934)
Number of Subjects with Secondary Definition of COVID-19, n (%)	121 (0.9)	6 (<0.1)
Number of Subjects Censored, n (%)	13762 (99.1)	13928 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.951 (0.889, 0.978)
Person-Years [2]	2695.0	2716.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	44.897 (37.255, 53.647)	2.209 (0.810, 4.807)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.951 (0.890, 0.982)

- [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.
- [2] Person-years is defined as the total years from randomization date to the date of secondary definition of COVID-19 or last date of study participation, 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 14.2.2.7.1.1

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=15180)
Number of Subjects with COVID-19, n (%)	92 (0.6)	6 (<0.1)
Number of Subjects Censored, n (%)	15078 (99.4)	15174 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.935 (0.852, 0.972)
Person-Years [2]	2940.1	2949.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	31.291 (25.225, 38.376)	2.034 (0.746, 4.427)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.935 (0.853, 0.977)

- [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 or last date of study participation, 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=14370)	mRNA-1273 (N=14312)
Number of Subjects with COVID-19, n (%)	90 (0.6)	6 (<0.1)
Number of Subjects Censored, n (%)	14280 (99.4)	14306 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.934 (0.848, 0.971)
Person-Years [2]	2786.5	2785.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	32.298 (25.972, 39.700)	2.154 (0.790, 4.688)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.933 (0.849, 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 or last date of study participation, 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=334)	mRNA-1273 (N=341)
Number of Subjects with COVID-19, n (%)	1 (0.3)	0
Number of Subjects Censored, n (%)	333 (99.7)	341 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	58.7	58.3
Incidence Rate per 1,000 Person-Years (95% CI) [3]	17.038 (0.431, 94.931)	0.000 (NE, 63.310)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-38.284, 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 or last date of study participation, 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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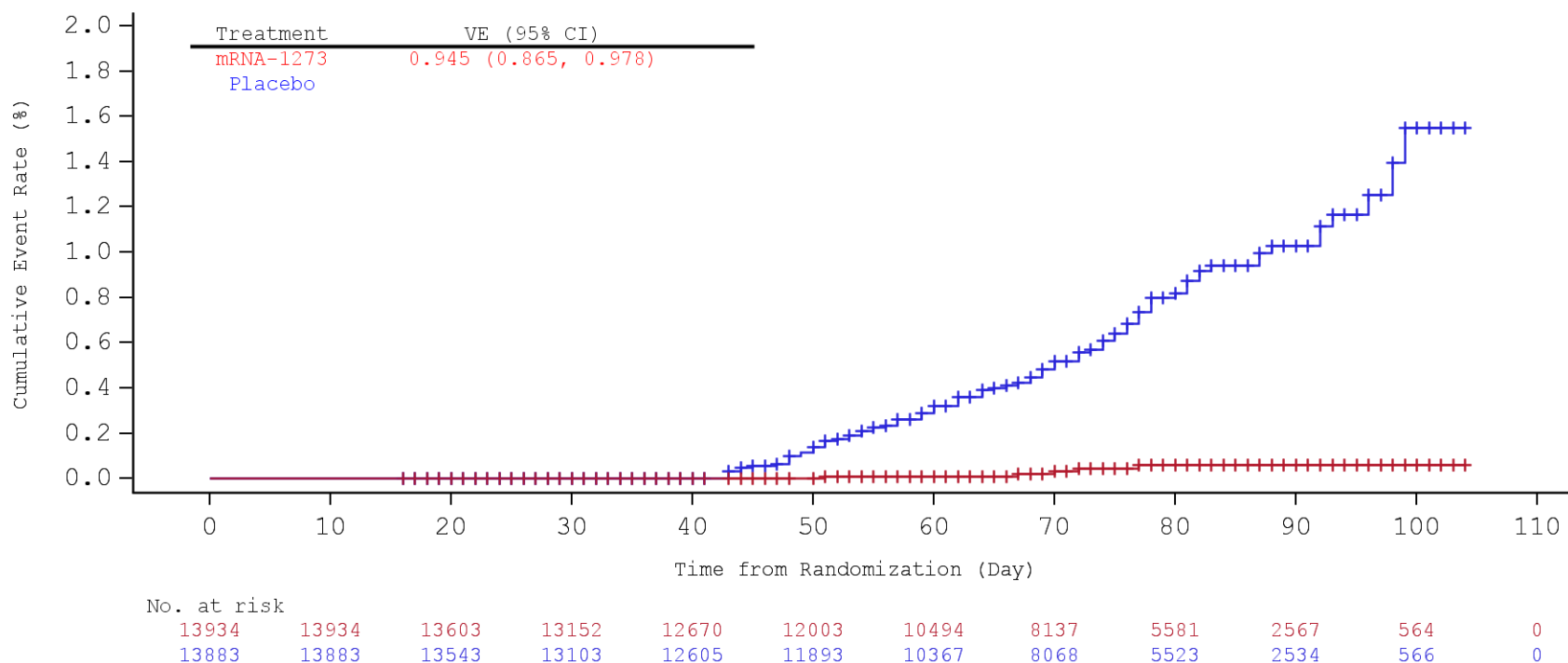
Table 14.2.2.7.2.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Starting 14 Days After Second Injection Regardless of Prior SARS-CoV-2 Infection
Full Analysis Set

	Placebo (N=15170)	mRNA-1273 (N=15180)
Number of Subjects with COVID-19, n (%)	111 (0.7)	7 (<0.1)
Number of Subjects Censored, n (%)	15059 (99.3)	15173 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.938 (0.866, 0.971)
Person-Years [2]	2932.2	2947.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	37.856 (31.142, 45.588)	2.375 (0.955, 4.893)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.937 (0.866, 0.975)

- [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.
- [2] Person-years is defined as the total years from randomization date to the date of COVID-19 or last date of study participation, 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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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



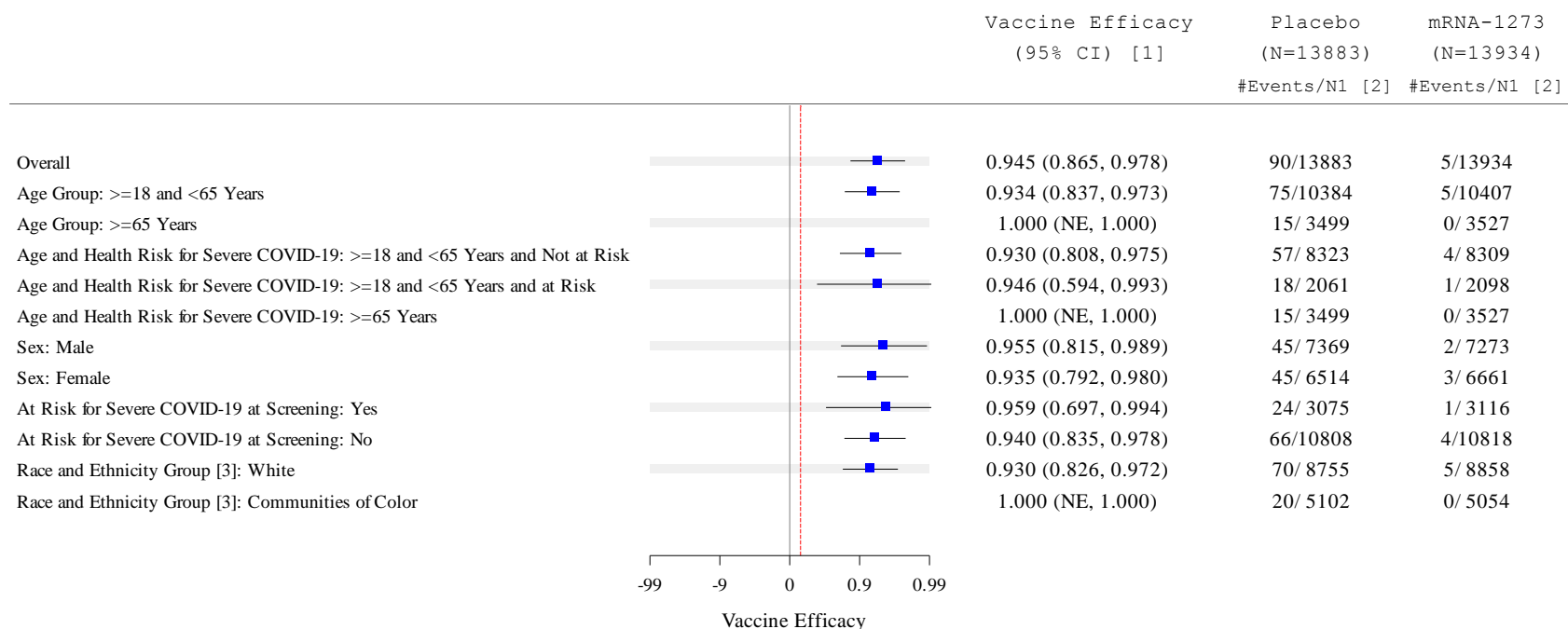
Source table: Table 14.2.2.1.1.1.1.

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.

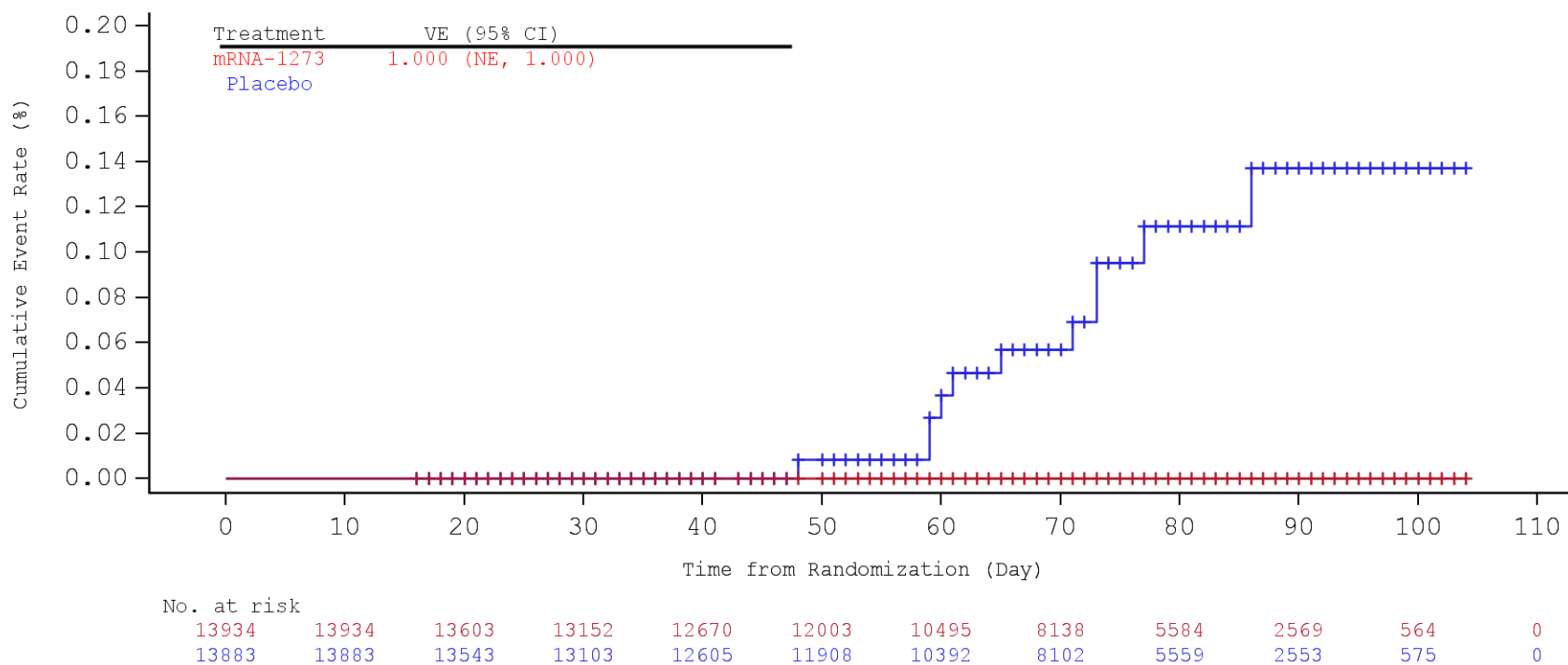
[1] Vaccine efficacy, defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[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.

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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



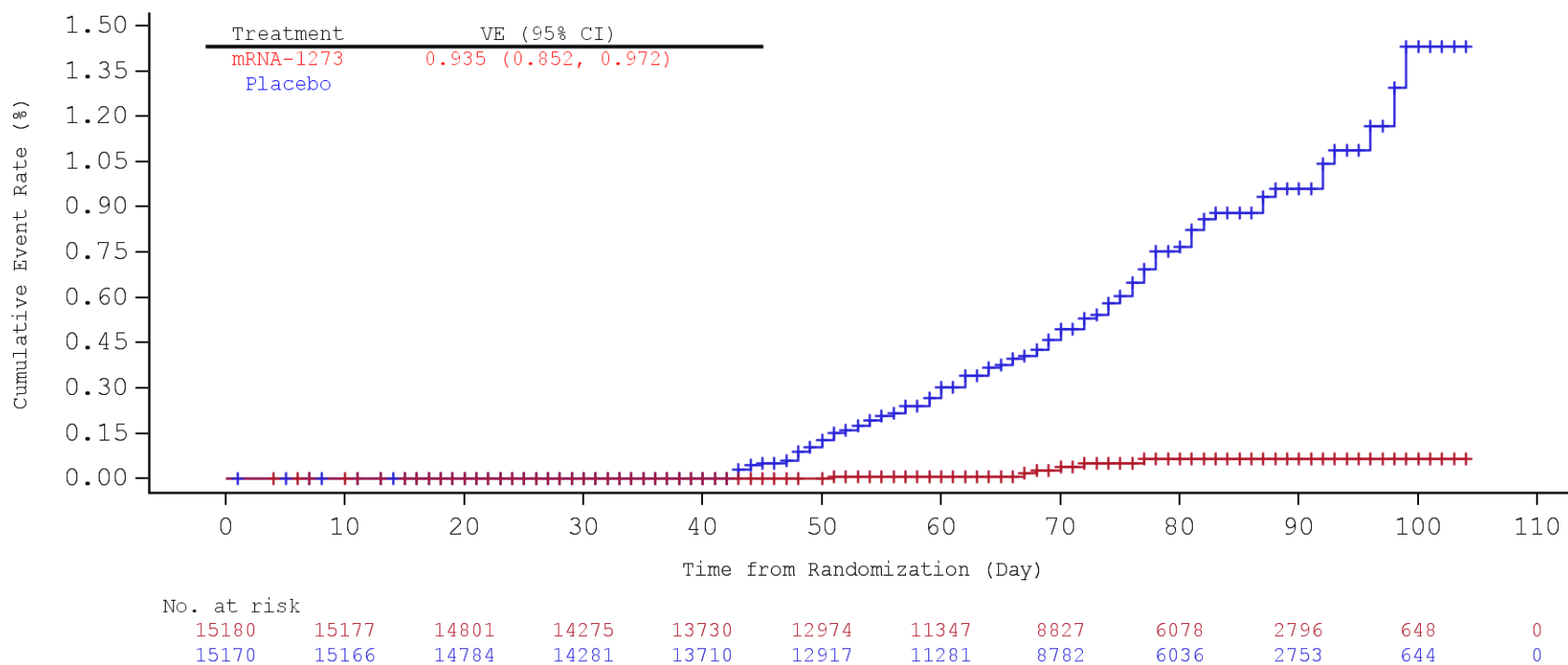
Source table: Table 14.2.2.2.1.1.1.

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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