Information Request for Shell Tables for BLA125752

Please complete the following shell tables to assist with our review of the clinical data submitted as part of your application. The data presented in these tables should align with the information presented in the Prescribing Information, where applicable.

We request that the shell tables be submitted as Word documents (.docx, font: Times New Roman, size 9-11). For some of the shell tables provided below, we have included partially completed columns or rows to serve as a model of how we would like the data presented, however we are amenable to additional formatting/editing as needed to accurately reflect and support the data included in each table that generally follow the requested format. Please ensure that all the tables are 508 compliant.

With each table, please include the appropriate table title, including the study population analyses set, as well as table footnotes that reference the source Clinical Study Report tables and appropriately define table content, including how study analyses populations are comprised and how adjustments are made based on statistical approaches. (*Note: Sample footnotes have been provided, but additional details may be needed, including but not limited to those outlined in red.)*

Table A: Clinical Trials Submitted in Support of Efficacy and Safety Determinations of the Moderna COVID-19 Vaccine mRNA-1273

Study Number	**Type of Study (Efficacy, Safety, Nonclinical)**	**Population (N)**	**Study Design and Type of Control**	**Test Product(s); Dosing Regimens; Dosage Forms; Routes of Administration; Duration**	**Study Status**

Table B. Study Disposition, Safety Set

	mRNA-1273 (N=) n (%)	Placebo (N=) n (%)	Total (N=) n (%)
Randomized			
Safety Set			
Solicited Safety Set			
First Injection Solicited Safety Set			
Second Injection Solicited Safety Set			
Original blinded, placebo-controlled follow-up period			
Completed 1 dose			
Completed 2 doses			
Median blinded follow up post dose 2			
Completed at least 6 months follow up post dose 2 in blinded phase			

Discontinued from original blinded placebo-controlled vaccination period			
Reason for discontinuation			
Add row for each reason			
Discontinued after dose 1 and before dose 2			
Discontinued after dose 2 and before unblinding			
Withdrawn from study			
Reason for withdrawal from study			
Add row for each reason			
Withdrawn from study after dose 1 and before dose 2			
Withdrawn from study after dose 2 and before unblinding			
	Original treatment group: mRNA-1273 (N=) n (%)	Original treatment group: Placebo (N=) n (%)	Total (N=) n (%)
Open label follow up period			
Chose to remain blinded			
Unblinded			
Unblinded and crossed over to receive mRNA-1273			
Completed dose 3			
Completed dose 4			
Unblinded and did not receive mRNA-1273			
Discontinued from vaccination during open label period			
Reason for discontinuation			
Add rows for each reason			
Discontinued after unblinding and prior to dose 3			
Discontinued after dose 3 but before dose 4			
Discontinued after dose 4			
Withdrawn from study during open label period			
Reason for withdrawal			
Add rows for each reason			
Withdrawn after unblinding and before dose 3			
Withdrawn after dose 3 and before dose 4			
Withdrawn after dose 4			

Source: Adapted from STN 125752.1_ P301 Cnical Study Report, Table X. N:____, n:____

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Table C. Study Disposition, Efficacy Analyses Population

	mRNA-1273 (N=) n (%)	Placebo (N=) n (%)	Total (N=) n (%)
Randomized			
Full Analysis Set			
mITT Set			
PP Set			
Excluded from PP Set			
Reason for exclusion			
Add rows for reasons			
Immunogenicity Subset			

Excluded from PP Immuno Subset			
Reason for exclusion			
Add rows for reasons			

Source: Adapted from STN 125752.1_ P301 Clinical Study Report, Table X. N:____, n:____.
Define each analyses set-

Table D. Follow up

	mRNA-1273 (N=) n (%)	Placebo (N=) n (%)	Total (N=) n (%)
Follow up during blinded phase			
Median blinded follow up post dose 2 (days)			
All participants			
18-65 years			
65 years and older			
At least 2 months blinded follow up post dose 2			
Between 2-4 months follow up post dose 2			
At least 4 months blinded follow up post dose 2			
Between 4-6 months follow up post dose 2			
At least 6 months blinded follow up post dose 2			
Follow up during open label phase			
Median total follow up (blinded + unblinded) after dose 2 of originally assigned treatment (days)			
All participants			
18-65 years			
65 years and older			
At least 6 months total follow up (blinded + unblinded) after dose 2 of originally assigned treatment			
In participants originally assigned to placebo and who crossed over to receive mRNA-1273:			
Median follow up post dose 4 (2 doses of mRNA-1273) (days)			
All participants			
18-65 years			
65 years and older			
At least 2 months follow up post dose 4			
All participants			
18-65 years			
65 years and older			

Source: Adapted from STN 125752.1_ P301 Clinical Study Report, Table X. N:____, n:____
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For Tables E and F below, please:
-provide separate demographics tables for the safety set and the per protocol set
-discuss/highlight if there are any differences in the numbers when looking at this for the original EUA vs for the updated safety/efficacy set for the BLA

Table E. Demographics and Other Baseline Characteristics

Characteristic	mRNA-1273 (N=) n (%)	Placebo (N=) n (%)	Total (N=) n (%)
Sex			
Female			

Male			
Age (years)			
Mean (SD)			
Median			
Min, Max			
Age subgroups (years)			
18 to <65			
65 and older			
Race			
American Indian or Alaska Native			
Asian			
Black or African American			
Native Hawaiian or Other Pacific Islander			
White			
Other			
Missing or unknown			
Ethnicity			
Hispanic or Latino			
Not Hispanic or Latino			
Missing or unknown			
Occupational Risk (*define in footnote)			
Healthcare worker			
High risk conditions (further define in footnote)**			
One high risk condition present			
Two or more high risk conditions present			
No high risk condition			
BMI: <30 kg/m^2			
BMI: ≥30 kg/m^2			
Age and Health Risk for Severe COVID-19			
18 to <65 years and not at risk			
18 to <65 years and at risk			
≥65 years			
Baseline SARS-CoV-2 status			
Negative			
Positive			
Missing or unknown			

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table X. N:____, n:____

Table F Protocol-Defined Risk for Severe COVID-19 Disease

Risk category	mRNA-1273 (N=) n (%)	Placebo (N=) n (%)	Total (N=) n (%)
Without any protocol risk for severe COVID-19			
With any protocol risk for severe COVID-19			
Chronic Lung Disease			
Significant cardiac disease			
Severe obesity			
Diabetes			
Liver disease			
HIV infection			

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table X. N:____, n:____

Table G. Updated Efficacy Analysis of primary endpoint, COVID-19 Starting 14 Days After the 2nd Dose, Per-Protocol Set (based on data cutoff for the BLA)

Primary Endpoint: COVID-19 (per adjudication committee assessment)	**mRNA-1273 N=; Cases /N (%) (Incidence rate per 1,000 person-years)**	**Placebo N=; Cases /N (%) (Incidence rate per 1,000 person-years)**	**Vaccine Efficacy (VE)% (95% CI)**
All participants			
18 to <65 years			
65 years and older			

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table X. N:____, n:____

Table H. Subgroup analysis of updated efficacy analysis, COVID-19 Starting 14 Days After the 2nd Dose, Per-Protocol Set (based on data cutoff for the BLA)

	mRNA-1273 N=; Cases /N (%) (Incidence rate per 1,000 person-years)	**Placebo N=; Cases /N (%) (Incidence rate per 1,000 person-years)**	**Vaccine Efficacy (VE)% (95% CI)**
Age			
18 to <65			
65 to <75			
75 and older			
Age and risk for severe COVID-19			
18 to <65 and not at risk			
18 to <65 and at risk			
65 and older and not at risk			
65 and older and at risk			
Sex			
Male			
Female			
Race			
American Indian or Alaska Native			
Asian			
Black or African American			
Native Hawaiian or Other Pacific Islander			
White			
Other			
Ethnicity			
Hispanic or Latino			
Not Hispanic or Latino			

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table X. N:____, n:____

Table I. Demographic characteristics of participants with COVID-19 starting 14 days after dose 2, based on updated efficacy analysis, Per-Protocol Set (based on data cutoff for the BLA)

	mRNA-1273 N=; n (%)	**Placebo N=; n (%)**	**Total N; n (%)**

Age			
18 to <65			
65 to <75			
75 and older			
Age and risk for severe COVID-19			
18 to <65 and not at risk			
18 to <65 and at risk			
65 and older and not at risk			
65 and older and at risk			
Sex			
Male			
Female			
Race			
American Indian or Alaska Native			
Asian			
Black or African American			
Native Hawaiian or Other Pacific Islander			
White			
Other			
Ethnicity			
Hispanic or Latino			
Not Hispanic or Latino			
High risk condition			
Yes			
No			
BMI ≥30			
BMI <30			

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table X. N:____, n:____

Table J. Subgroup analysis of updated efficacy analysis by risk factor, COVID-19 Starting 14 Days After the 2nd Dose, Per-Protocol Set (based on data cutoff for the BLA)

	mRNA-1273 N=; Cases /N (%) (Incidence rate per 1,000 person-years)	**Placebo N=; Cases /N (%) (Incidence rate per 1,000 person-years)**	**Vaccine Efficacy (VE)% (95% CI)**
High risk condition			
Yes			
No			
Risk Factor			
Chronic Lung Disease			
Significant Cardiac Disease			
Severe Obesity			
Diabetes			
Liver Disease			
HIV infection			
BMI: <30 kg/m^2			
BMI: ≥30 kg/m^2			

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table X. N:____, n:____

Table K. Subgroup analysis of updated efficacy analysis by baseline SARS-CoV-2 status, COVID-19 Starting 14 Days After the 2nd Dose, Full Analysis Set (based on data cutoff for the BLA)

Baseline SARS-CoV-2	**mRNA-1273 N=; Cases /N (%) (Incidence rate per 1,000 person-years)**	**Placebo N=; Cases /N (%) (Incidence rate per 1,000 person-years)**	**Vaccine Efficacy (VE)% (95% CI)**
Regardless of baseline SARS-CoV-2 status			
Positive			
Negative			
Unknown or missing			

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table X. N:____, n:____

Table L. Updated analysis of secondary efficacy endpoints, COVID-19 Starting 14 Days After the 2nd Dose, PPS (based on data cutoff for the BLA)

	mRNA-1273 N=; Cases /N (%) (Incidence rate per 1,000 person-years)	**Placebo N=; Cases /N (%) (Incidence rate per 1,000 person-years)**	**Vaccine Efficacy (VE)% (95% CI)**
Severe COVID-19			
All participants			
18 to <65 years			
65 years and older			
Secondary (CDC) definition of COVID-19			
All participants			
18 to <65 years			
65 years and older			
SARS-CoV-2 Infection (regardless of symptoms)			
All participants			
18 to <65 years			
65 years and older			
Deaths caused by COVID-19			
All participants			
18 to <65 years			
65 years and older			
Asymptomatic infection			
All participants			
18 to <65 years			
65 years and older			
Based on N-serology only			
Based on positive PCR only			

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table X. N:____, n:____

Table M. Updated Demographics Characteristics of Participants with severe COVID-19 starting 14 days after dose 2, PPS (based on data cutoff for BLA)

Characteristic	mRNA-1273 (N=) n (%)	Placebo (N=) n (%)	Total (N=) n (%)
Sex			
Female			
Male			
Age			
18 to <65			
65 to <75			
75 and older			
Race			
American Indian or Alaska Native			
Asian			
Black or African American			
Native Hawaiian or Other Pacific Islander			
White			
Other			
Ethnicity			
Hispanic or Latino			
Not Hispanic or Latino			
High risk conditions (further define in footnote)			
One high risk condition present			
Two or more high risk conditions present			
No high risk condition			
BMI: <30 kg/m^2			
BMI: ≥30 kg/m^2			

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table X. N:____, n:____

Table N. Updated subgroup analysis of vaccine efficacy against severe COVID-19 starting 14 days after Dose 2, PPS (based on data cutoff for BLA)

	mRNA-1273 N=; Cases /N (%) (Incidence rate per 1,000 person-years)	**Placebo N=; Cases /N (%) (Incidence rate per 1,000 person-years)**	**Vaccine Efficacy (VE)% (95% CI)**
Sex			
Female			
Male			
Age			
18 to <65			
65 and older			
Race			
American Indian or Alaska Native			
Asian			
Black or African American			
Native Hawaiian or Other Pacific Islander			
White			

Other			
Ethnicity			
Hispanic or Latino			
Not Hispanic or Latino			
High risk conditions (further define in footnote)			
Yes			
No			
BMI: <30 kg/m^2			
BMI: ≥30 kg/m^2			
Baseline SARS-CoV-2 status (based on FAS)			
Positive			
Negative			

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table X. N:____, n:____

Figure 1. Cumulative incidence curve of COVID-19 cases over time (vaccine vs placebo) (based on data cutoff for the BLA)

Table O. Updated analysis of COVID-19 cases from randomization by time period—FAS (based on data cutoff for the BLA)

First COVID-19 occurrence	**mRNA-1273 N=; Cases /N (%) (Incidence rate per 1,000 person-years)**	**Placebo N=; Cases /N (%) (Incidence rate per 1,000 person-years)**	**Vaccine Efficacy (VE)% (95% CI)**
Any time after dose 1			
Any time after dose 1 to before dose 2			
14 days after dose 1 to before 14 days after dose 2			
Any time after dose 2			
Dose 2 to before 14 days after dose 2			
14 days after dose 2 to <2 months after dose 2			
2 months after dose 2 to <4 months after dose 2			
≥4 months after dose 2			
First severe COVID-19 occurrence			
Any time after dose 1			
Any time after dose 1 to before dose 2			
14 days after dose 1 to before 14 days after dose 2			
Any time after dose 2			
Dose 2 to before 14 days after dose 2			
14 days after dose 2 to <2 months after dose 2			

2 months after dose 2 to <4 months after dose 2			
≥4 months after dose 2			

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table X. N:____, n:____

Table P. Updated analysis of all cause mortality from after randomization (based on data cutoff for the BLA)

	mRNA-1273 N=; Cases /N (%)	**Placebo N=; Cases /N (%)**	**(VE)% (95% CI)**
All participants			
18-65 years			
65 and older			

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table X. N:____, n:____

For Table Q and R and all severe COVID-19 cases (similar to excel tables you submitted for the EUA), please also provide in excel format.

Please also provide excel doc listing all COVID-19 cases in the mRNA-1273 arm (includes subject ID, age/sex, risk factors, date of onset of COVID-19, dates of vaccination).

Table Q. Deaths from COVID-19 (based on data cutoff for the BLA)

Study arm	**Subject ID**	**Age/sex**	**Risk factors**	**Date of onset of COVID-19**	**Date of death**	**Date of dose 1**	**Date of dose 2**	**Date of dose 3**	**Date of dose 4**
	e.g., Subject #00001	75M	Chronic lung disease	11/20/20	11/25/20	9/10/20 (placebo)	10/10/20 (placebo)	n/a	n/a

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table X. N:____, n:____

Table R. Participants with multiple, separate, symptomatic confirmed COVID-19 (based on data cutoff for the BLA)

Study arm	**Subject ID**	**Date of onset of COVID-19 episode 1**	**Additional info re: episode 1**	**Date of onset of COVID-19 episode 2**	**Additional info re: episode 2**	**Date of dose 1**	**Date of dose 2**	**Date of dose 3**	**Date of dose 4**
	e.g., Subject #123456	12/10/20	Severe COVID-19	3/10/21	Met CDC definition only, not protocol case definition	9/10/20 (placebo)	10/10/20 (placebo)	2/10/21 (mRNA-1273)	Scheduled, but not yet administered as of data cutoff

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table X. N:____, n:____

Table S. Summary of SARS-CoV-2 Variants of Concern or Variants of Interest for first COVID-19 occurrence from 14 days after dose 2 in cases that were sequenced, PPS (based on data cutoff for the BLA)

	mRNA-1273 N=; n (%)	**Placebo N=; n (%)**	**Total** N=; n (%)
Confirmed cases that			

were sequenced			
Confirmed cases that were not sequenced			
Unknown (indeterminate results or QNS samples)			
In sequenced cases, SARS-CoV-2 lineage identified			
e.g. B.1.1.7			
List each lineage			

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table X. N:____, n:____

Safety Results:

Please also complete Table T for overall study population and:

a. **By baseline SARS-CoV-2 status (positive and negative)**
b. **By demographics (race, ethnicity, sex, presence of high risk condition)**
c. **By age group (18 to <65, 65 and older)**

Table T. Safety Overview

Subjects reporting at least one	**mRNA-1273 n/N (%)**	**Placebo n/N (%)**
Immediate AE within 30 minutes after vaccination		
Dose #1		
Dose #2		
Solicited injection site reaction within 7 days		
Dose #1		
Dose #2		
Grade 3 or 4 solicited injection site reaction (any dose)		
Solicited systemic AR within 7 days		
Dose #1		
Dose #2		
Grade 3 or 4 systemic AR (any dose)		
Unsolicited Adverse Event		
Non-serious unsolicited adverse event		
Related non-serious unsolicited AE		
Grade 3 non-serious unsolicited AE		
Related Grade 3 non-serious unsolicited AE		
Medically Attended Adverse Event		
Related MAAE		
SAE		
Related SAE		
AESI (further define in footnote)		
Related AESI		
Deaths		
AE leading to discontinuation of the vaccine		

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table X. N:____, n:____

Solicited Adverse Events

Please also complete Tables U, V, W, and X for overall study population and by:
- baseline SARS-CoV-2 status (positive and negative)
-age (18 to <65, 65 and older)

Table U. Frequency of Solicited Local Reactions Within 7 Days After Each Dose, by Maximum Severity

Event	mRNA-1273 Dose 1 N= n (%)	Placebo Dose 1 N= n (%)	mRNA-1273 Dose 2 N= n (%)	Placebo Dose 2 N= n (%)
Any solicited local reaction				
Grade 1				
Grade 2				
Grade 3				
Grade 4				
Pain				
Any				
Grade 1				
Grade 2				
Grade 3				
Grade 4				
Erythema				
Any				
Grade 1				
Grade 2				
Grade 3				
Grade 4				
Swelling				
Any				
Grade 1				
Grade 2				
Grade 3				
Grade 4				
Axillary swelling/tenderness				
Any				
Grade 1				
Grade 2				
Grade 3				
Grade 4				

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table X. N:____, n:____

Table V. Frequency of Delayed Local Injection Site Reactions (onset after 7 days)

Event	mRNA-1273 Dose 1 N= n (%)	Placebo Dose 1 N= n (%)	mRNA-1273 Dose 2 N= n (%)	Placebo Dose 2 N= n (%)
Any				
Severe				
Medically attended				
SAE				
Day of onset: median (min, max)				
Duration: median (min, max)				
Breakdown by reaction				

e.g., erythema, any				
severe				
Day of onset: median (min, max)				
Duration: median (min, max)				

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table X. N:____, n:____

Create similar table as Table V (if applicable) for delayed onset systemic reaction (onset after 7 days)

Table W. Frequency of Solicited Systemic Adverse Events Within 7 Days After Each Dose, by Maximum Severity

Event	mRNA-1273 Dose 1 N= n (%)	Placebo Dose 1 N= n (%)	mRNA-1273 Dose 2 N= n (%)	Placebo Dose 2 N= n (%)
Any systemic AR				
Grade 1				
Grade 2				
Grade 3				
Grade 4				
Fever				
≥38.0℃				
38.0℃ to 38.4℃				
38.5℃ to 38.9℃				
39℃ to 40.0℃				
>40.0℃				
Headache				
Any				
Grade 1				
Grade 2				
Grade 3				
Grade 4				
Fatigue				
Any				
Grade 1				
Grade 2				
Grade 3				
Grade 4				
Myalgia				
Any				
Grade 1				
Grade 2				
Grade 3				
Grade 4				
Arthralgia				
Any				
Grade 1				
Grade 2				
Grade 3				
Grade 4				
Nausea/vomiting				
Any				

Grade 1				
Grade 2				
Grade 3				
Grade 4				
Chills				
Any				
Grade 1				
Grade 2				
Grade 3				
Grade 4				
Use of antipyretic or pain medication				

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table X. N:____, n:____

Please define grade for solicited reactions

Table X. Characteristics of Solicited Local and Systemic Adverse Reactions

Event	mRNA-1273 Dose 1	Placebo Dose 1	mRNA-1273 Dose 2	Placebo Dose 2
Any solicited local reaction				
Day of onset: median (min, max)	Day (min, max)	Day (min, max)	Day (min, max)	Day (min, max)
Duration: median (min, max)	Days (min, max)	Days (min, max)	Days (min, max)	Days (min, max)
Persisted beyond 7 days				
e.g, Pain				
Day of onset: median (min, max)	Day (min, max)	Day (min, max)	Day (min, max)	Day (min, max)
Duration: median (min, max)	Days (min, max)	Days (min, max)	Days (min, max)	Days (min, max)
Persisted beyond 7 days				
Any solicited systemic reaction				
Day of onset: median (min, max)	Day (min, max)	Day (min, max)	Day (min, max)	Day (min, max)
Duration: median (min, max)	Days (min, max)	Days (min, max)	Days (min, max)	Days (min, max)
Persisted beyond 7 days				
e.g. Myalgia				
Day of onset: median (min, max)	Day (min, max)	Day (min, max)	Day (min, max)	Day (min, max)
Duration: median (min, max)	Days (min, max)	Days (min, max)	Days (min, max)	Days (min, max)
Persisted beyond 7 days				

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table X. N:____, n:____

Table Y. Frequency of Unsolicited AEs with Occurrence in ≥1% of Participants in Any Treatment Group

Primary System Organ Class (CODE)	Preferred Term (CODE)	mRNA-1273 (N=) Any % (Severe %)	Placebo (N=) Any % (Severe %)
Each SOC	Adverse events in any PT Any PT (% severe) Any PT (% severe)		
Each SOC	Adverse events in any PT Any PT (% severe) Any PT (% severe)		

Adverse events in any PT = at least one adverse event experienced (regardless of the MedDRA Preferred Term)
N = number of subjects included in the considered cohort in each group
n/% = number/percentage of subjects reporting the adverse event at least once [n] = number of events reported
*All randomized participants who receive at least 1 dose of the study intervention.

Please also complete the following 'SAE' Tables that provide the proportion of participants by study group for the respective age cohorts who report the following:

a. 18 to <65 years
- within 7 days of any dose
- within 28 days of any dose
- through data-cut

b. 65 and older
- within 7 days of any dose
- within 28 days of any dose
- through data-cut

Please also complete the following 'AEs Leading to Study Withdrawal' Tables that provide the proportion of participants by study group for the respective age cohorts who report the following:

b. 18 to <65 years
- within 7 days of any dose
- within 28 days of any dose
- throughout study

c. 65 and older
- within 7 days of any dose
- within 28 days of any dose
- through data-cut

Table Z. Percentage of Subjects Reporting SAEs, by MedDRA Primary System Organ Class and Preferred Term

Primary System Organ Class (CODE)	Preferred Term (CODE)	mRNA-1273 (N=) n (%) [n]	Placebo (N=) n (%) [n]
Each SOC	Adverse events in any PT Each PT Each PT Each PT		

Each SOC	Adverse events in any PT Each PT Each PT Each PT		

Adverse events in any PT = at least one adverse event experienced (regardless of the MedDRA Preferred Term)
N = number of subjects included in the considered cohort in each group
n/% = number/percentage of subjects reporting the adverse event at least once [n] = number of events reported

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SMQ analyses

Please conduct broad and narrow SMQs for each of disorders listed below showing the hierarchical structure of the SMQ. For each SMQ, please provide one table that includes broad and narrow SMQs combined and another table that lists only narrow SMQs. Across study groups, please specify the # of events reported and the # of participants who reported each listed event. *Please include in the footnotes- the MedDRA version used as well as the SMQ version (ie, 23.0).*

List of SMQs

- Embolic & Thrombotic Events
- Hearing & Vestibular Disorders
- Angioedema
- Arthritis
- Convulsions
- CNS Vascular Disorders
- Hypersensitivity
- Peripheral Neuropathy
- Demyelination
- Thrombophlebitis
- Vasculitis
- Hematopoietic Cytopenias
- Cardiomyopathy→ for this SMQ, please present additional breakdowns by sex and age (males overall, females overall, 18-30 overall, 18-30 male, 18-30 female, 30-60, 60+)

For each SMQ:

1. The proportion of participants who had completed 1 dose and 2 doses (mean or per participant)
2. Follow-up duration after the 2nd dose (either median, or per participant f/up duration)
3. Please submit the tables in Excel format, in addition to Word.
4. Additional Custom MedDRA Queries may be requested following review of the submission,
5. *Case summaries for participants who reported AEs that were included in each SMQ may also be requested*

For Tables AA, BB, CC, please also submit in excel format.

Table AA. SAEs considered related by Investigator

Product (Vaccine or Placebo)	**Participant ID#**	**Age/sex**	**Number of doses**	**Days since last dose**	**SAE**	**Risk Factors**	**Resolution**	**Related per Moderna**
		28F	2	1	e.g. brachial nerve neuritis	none	Resolved	Yes

Table BB. AESIs

Product (Vaccine or Placebo)	Participant ID#	Age/sex	Number of doses	Days since last dose	AESI	Risk Factors	Resolution	Related per Investigator/ Moderna
e.g, mRNA-1273		18M	2	1	Myocarditis	none	Resolving	Yes/Yes

Table CC. Deaths

Product (Vaccine or Placebo)	Participant ID#	Age/Sex	Number of doses	Days since last dose	Cause of death	Risk Factors
e.g, mRNA-1273		78M	2	50	Cardiac arrest	history of MI, s/p 2 stents

Table DD. Pregnancies, based on original randomization

	mRNA-1273 N; n (%)	Placebo N; n (%)	Total N; n (%)
Total number of pregnancies			
Timing of pregnancy			
Completed 1 dose			
Completed 2 doses			
Timing of last dose relative to pregnancy			
Within 30 days of pregnancy			
>30 days after pregnancy			
Outcomes			
e.g., Spontaneous Abortions			
Elective Abortions			
Delivered full term			
List others			

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table X. N:____, n:____

Provide separate similar table for participants who experienced pregnancy who were originally randomized to placebo and then crossed over to receive mRNA-1273 after unblinding