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Overview of Moderna COVID-19 Vaccine (mRNA-1273)

DRAFT WHO SAGE Meeting – January 21, 2021

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Forward-looking statements and disclaimer

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Outline of Presentation

- Brief review of :
  - mRNA platform
  - Preclinical studies
  - Phase 1 & 2 trials
- Phase 3 safety & efficacy trial
- Brief review of vaccine storage & handling
- Summary
- Q & A

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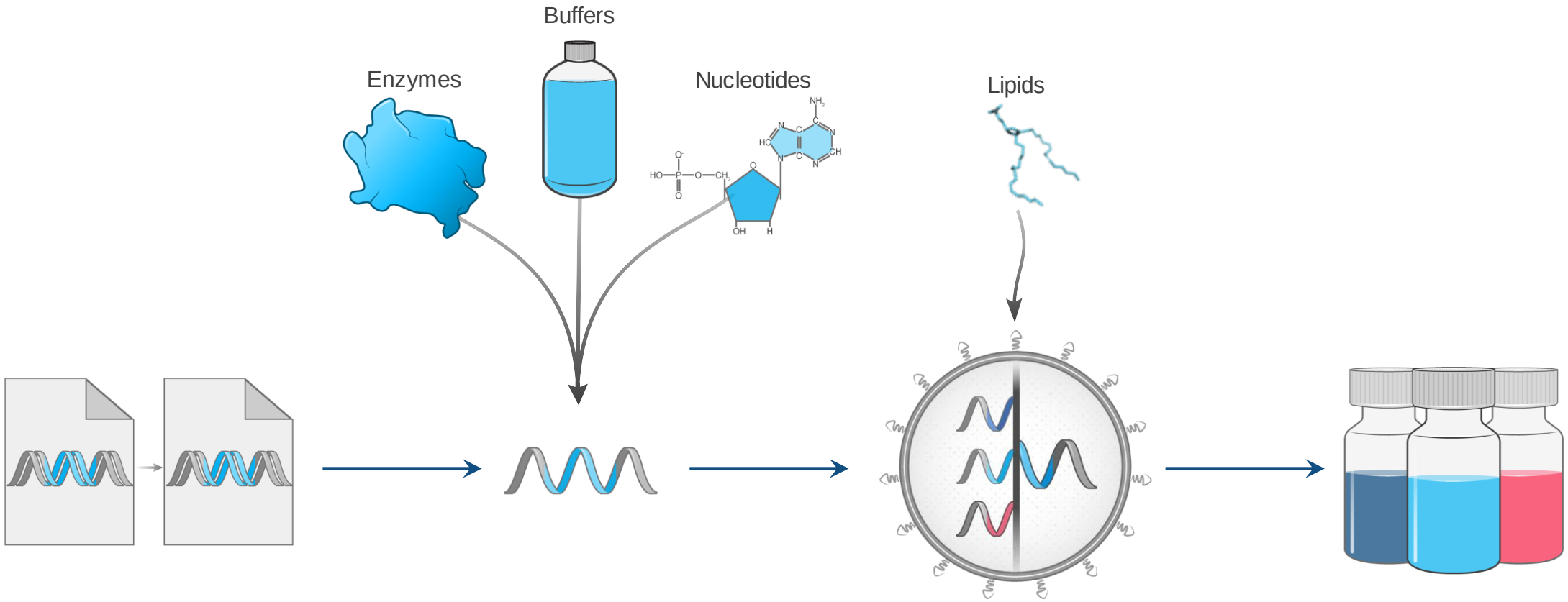
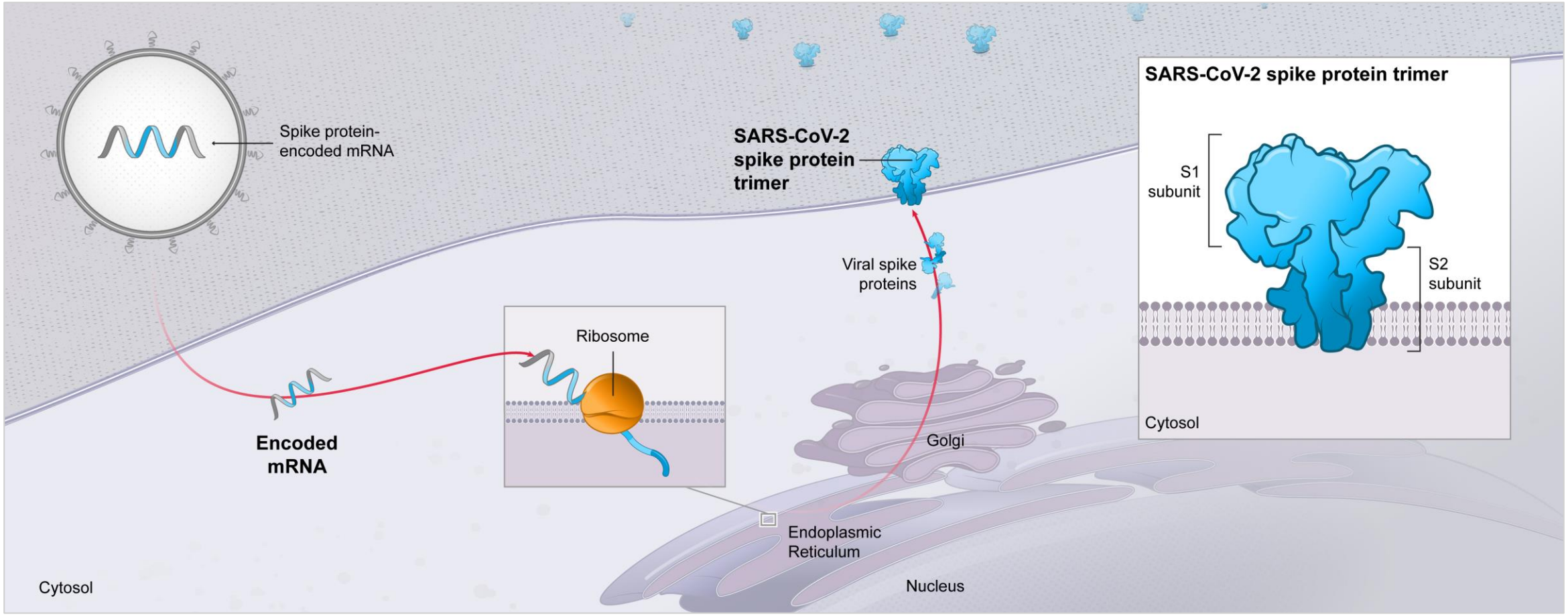
mRNA Platform

A Known DNA (or RNA) Sequence Can Serve as the Basis for an mRNA Vaccine, Which is then Formulated with Lipid Nanoparticles (LNPs)



mRNA-1273 encodes for the full-length Spike Protein in the Pre-fusion Conformation (S-2P)



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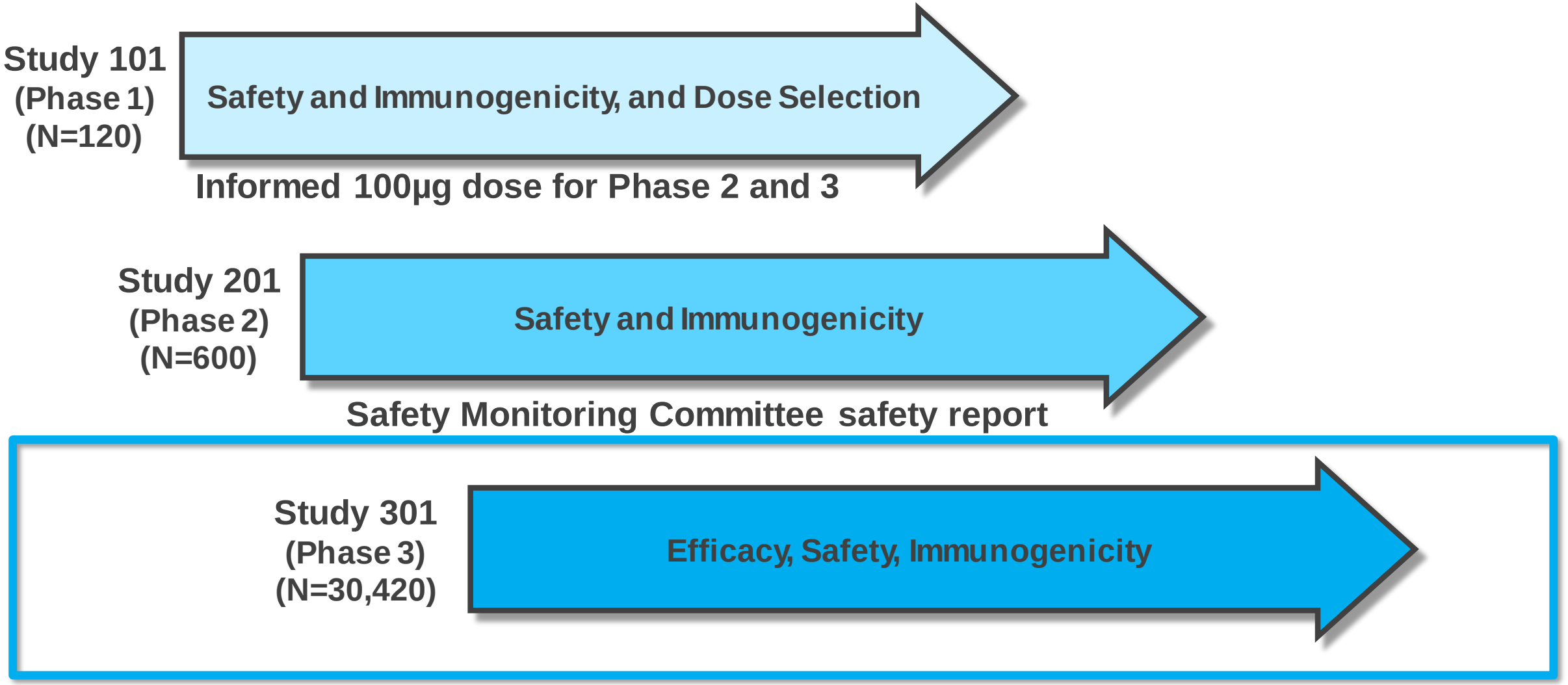
mRNA-1273 Preclinical & Clinical Programs

mRNA-1273 Non-clinical Results

- Immunogenic
  - Drives robust SARS-CoV-2-specific neutralizing antibody and Th1-directed CD4+ and CD8+ T-cell responses
- Nonclinical animal challenge studies demonstrate
  - Full protection of mice, hamsters and non-human primates from SARS-CoV-2
  - Does not lead to vaccine-associated enhanced respiratory disease
- No safety concerns identified in developmental and reproductive toxicology study (DART)

Studies were performed in young and aged mice, Golden Syrian Hamster, and rhesus macaque (NHP) animal models

mRNA-1273 Full Development Program Supports the 100-µg Dose



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Summary of Phase 1 and 2 studies with mRNA-1273 Immunogenicity Data

- Neutralizing antibody titers observed in all participants following 2nd dose
- GMTs across age strata numerically higher than in pool of convalescent sera
- Neutralizing antibodies persisted for at least 3 months after 2nd dose and remained numerically higher than convalescent sera
- Strong Th-1 dominant, CD4+ T-cell response observed
  - Consistent results with preclinical studies

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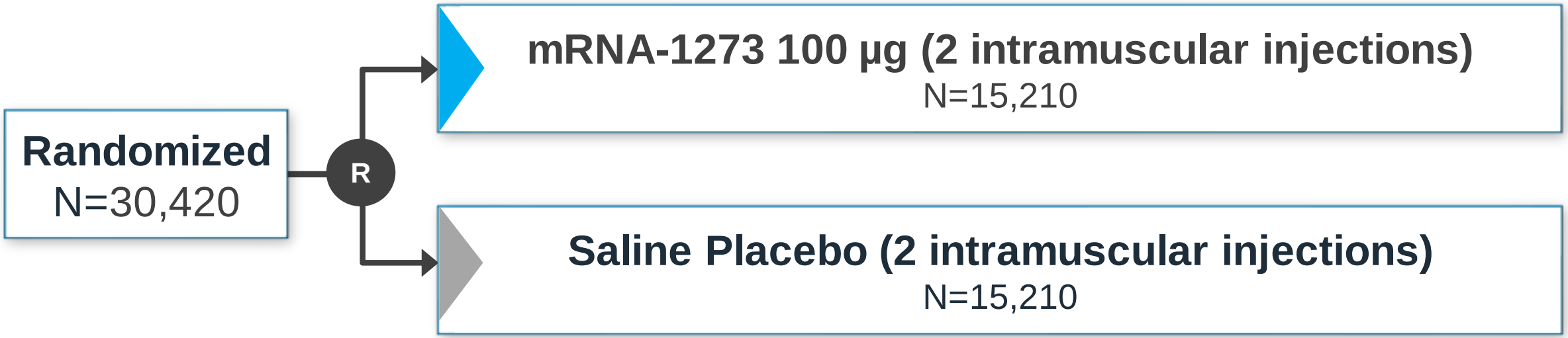
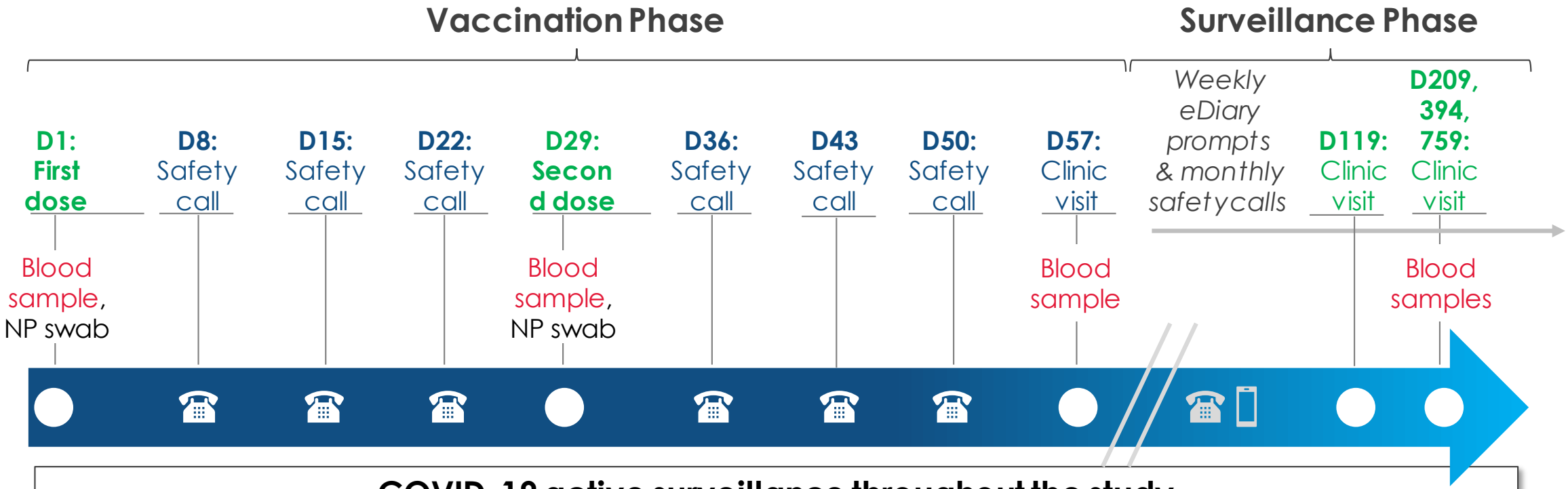
Study 301 – Large Scale, Phase 3 Safety & Efficacy Trial

Study 301: Pivotal, Randomized, Placebo-Controlled Evaluation of Efficacy and Safety



Study 301: Scheduled Visits and Safety Calls



COVID-19 active surveillance throughout the study
Daily telemedicine visits for participants with COVID-19
eDiary captures solicited local and systemic adverse reactions in all participants
SAEs and MAAEs captured throughout the study

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Study 301 Primary Objective: Case Definition of Symptomatic COVID-19 Disease

- Symptoms
  - ≥ 2 systemic: fever, chills, myalgia, headache, sore throat, new olfactory and taste disorder(s)

OR

  - ≥ 1 respiratory: cough, shortness of breath / difficulty breathing, clinical or radiographical evidence of pneumonia

AND

- Confirmed SARS-CoV-2 infection via RT-PCR

Primary analysis: adjudicated cases occurring ≥ 14 days after dose 2

Study 301 Key Secondary Objective: Case Definition of Severe COVID-19

- Confirmed COVID-19 as per the Primary Endpoint definition, plus <u>any one</u> of the following:
  - Clinical signs indicative of severe systemic illness, RR ≥ 30 per minute, HR ≥ 125 BPM, SpO_2 ≤ 93% on room air at sea level or PaO_2/FIO_2 < 300 mm Hg
  - Respiratory failure or ARDS, evidence of shock (SBP < 90 mm Hg, DBP < 60 mm Hg or requiring vasopressors)
  - Significant acute renal, hepatic or neurologic dysfunction
  - Admission to ICU or death

RR: respiratory rate; HR: heart rate; BPM: beats per minute; SpO_2: oxygen saturation; PaO_2/FIO_2: arterial oxygen partial pressure over fractional inspired oxygen; mm Hg: pressure measured by millimeters of mercury; ARDS: acute respiratory distress syndrome; SBP: systolic blood pressure; DBP: diastolic blood pressure; ICU: intensive care unit

Study 301: Representation of Participants with Risk Factors

Full Analysis Set

	mRNA-1273 N=15,181		Placebo N=15,170	
	n	%	n	%
Age and health risk for severe COVID-19				
18 to < 65 without comorbid conditions	8,888	**59%**	8,886	**59%**
18 to < 65 with comorbid conditions	2,530	**17%**	2,535	**17%**
≥ 65 with and without comorbid conditions	3,749	**25%**	3,749	**25%**

Comorbid conditions included chronic lung disease or moderate to severe asthma, significant cardiac disease, severe obesity, diabetes, liver disease, stable HIV infection

Study 301: Representative of US Demography

Full Analysis Set

	mRNA-1273 N=15,181		Placebo N=15,170	
	n	%	n	%
Sex, male	7,923	**52%**	8,062	**53%**
Age, years				
Mean (SD)	**51 (15.5)**		**51 (15.6)**	
Age group				
≥ 18 to < 65	11,413	**75%**	11,418	**75%**
≥ 65	3,768	**25%**	3,752	**25%**
Breakdown of ≥ 65 age group				
≥ 65 to < 70	1,905	**51%**	1,817	**48%**
≥ 70 to < 75	1,205	**32%**	1,194	**32%**
≥ 75 to < 80	467	**12%**	507	**14%**
≥ 80	191	**5%**	234	**6%**

Race/Ethnicity Enrollment Distribution Compared to US Population

Full Analysis Set

Race	Study 301 (N=30,351) %	US Population %
White	79.2%	75.0%
Black or African American	10.2%	14.2%
Asian	4.6%	6.8%
More than one race	2.1%	3.4%
American Indian or Alaska Native	0.8%	1.7%
Hawaiian or other Pacific Islander	0.2%	0.4%
Other	2.1%	5.5%
Not reported or unknown	0.9%	0%
Ethnicity		
Hispanic or Latino	20.5%	18.4%

EDC, US Census Bureau: ACS Demographic Estimate

Study 301: 23% of Participants Reported ≥ 1 Pre-Existing Medical Risk Factor

Full Analysis Set

Medical Risk Factor	mRNA-1273 N=15,181		Placebo N=15,170	
	n	%	n	%
Diabetes	1,435	9%	1,440	9%
Severe obesity (BMI >40 kg/m^2)	1,025	7%	1,021	7%
Chronic lung disease	710	5%	744	5%
Significant cardiac disease	752	5%	744	5%
Liver disease	100	< 1%	96	< 1%
HIV	92	< 1%	87	< 1%

Study 301: Primary Efficacy Objective Met, VE Against Confirmed, Symptomatic COVID-19 Cases is > 94%

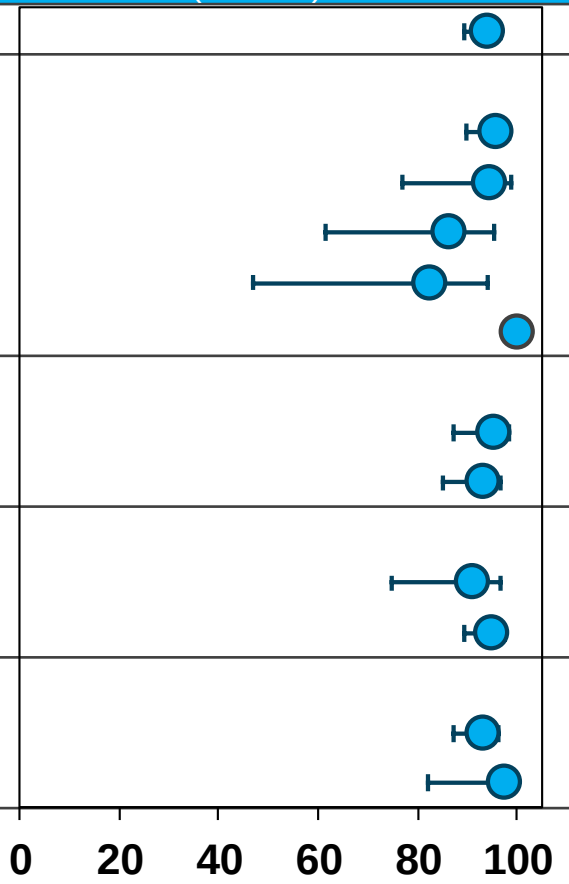
Per Protocol

Confirmed, Symptomatic COVID-19 Cases	Primary Efficacy Analysis mRNA-1273 N=14,134	 Placebo N=14,073
Number of cases, n (%)	11 (< 0.1%)	185 (1.3%)
Vaccine efficacy based on hazard ratio (95% CI)	94.1% (89.3%, 96.8%)	
p-value	< 0.0001	
Incidence rate per 1000 person-years	3.3	56.5

Study 301: Subgroup Analyses of Efficacy are Consistent with Primary Analysis

Per Protocol — Primary Efficacy Analysis

Subgroup	# Events / N: mRNA-1273 N=14,134	# Events / N: Placebo N=14,073	Vaccine Efficacy (95% CI)	Vaccine Efficacy (95% CI)
Overall	11 / 14,134	185 / 14,073		**94.1%** (89.3%, 96.8%)
Age and risk				
18 to < 65 without comorbidities	5 / 8,396	121 / 8,403		**95.9%** (90.0%, 98.3%)
18 to < 65 with comorbidities	2 / 2,155	35 / 2,118		**94.4%** (76.9%, 98.7%)
≥ 65 with or without comorbidities	4 / 3,583	29 / 3,552		**86.4%** (61.4%, 95.2%)
65 to < 75 with or without comorbidities	4 / 2,953	22 / 2,864		**82.4%** (46.9%, 93.9%)
≥ 75 with or without comorbidities	0 / 630	7 / 688		**100%** (NE, 100)
Sex				
Male	4 / 7,366	87 / 7,462		**95.4%** (87.4%, 98.3%)
Female	7 / 6,768	98 / 6,611		**93.1%** (85.2%, 96.8%)
Participants with comorbidities (all ages)				
Yes	4 / 3,206	43 / 3,167		**90.9%** (74.7%, 96.7%)
No	7 / 10,928	142 / 10,906		**95.1%** (89.6%, 97.7%)
Race and Ethnicity				
Non-Hispanic White	10 / 9,023	144 / 8,916		**93.2%** (87.1%, 96.4%)
Communities of Color	1 / 5,088	41 / 5,132		**97.5%** (82.2%, 99.7%)



NE: not estimable

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Study 301: Consistent Reduction in Symptomatic, Confirmed COVID-19 Regardless of Racial Group

Per Protocol – Primary Efficacy Analysis

	# Events / N		Vaccine Efficacy (95% CI)
	mRNA-1273	Placebo	
Overall	**11 / 14,134**	**185 / 14,073**	**94.1%** (89.3, 96.8)
White	**11 / 11,253**	**166 / 11,174**	**93.5%** (88.0, 96.5)
Black or African American	**0 / 1,385**	**6 / 1,349**	**100%**
Asian	**0 / 620**	**5 / 689**	**100%**
American Indian or Alaska Native	**0 / 108**	**1 / 111**	**100%**
Native Hawaiian or Other Pacific Islander	**0 / 35**	**0 / 31**	**NE**
Other	**0 / 299**	**2 / 295**	**100%**
Multiple	**0 / 295**	**3 / 307**	**100%**
Not Reported	**0 / 86**	**1 / 64**	**100%**
Unknown	**0 / 53**	**1 / 53**	**100%**

Study 301: Consistent Reduction in Symptomatic, Confirmed COVID-19 Regardless of Ethnicity

Per Protocol – Primary Efficacy Analysis

	# Events / N		Vaccine Efficacy (95% CI)
	mRNA-1273	Placebo	
Overall	**11 / 14,134**	**185 / 14,073**	**94.1%** (89.3, 96.8)
Hispanic or Latino	**1 / 2,789**	**28 / 2,780**	**96.5%** (74.4, 99.5)
Not Hispanic or Latino	**10 / 11,212**	**156 / 11,165**	**93.7%** (88.1, 96.7)
Not reported	**0 / 97**	**0 / 76**	**NE**
Unknown	**0 / 36**	**1 / 52**	**100% (NE, 100)**

NE: Not Estimable

Study 301: Consistent Reduction in Symptomatic, Confirmed COVID-19 Regardless of Comorbidity

Per Protocol – Primary Efficacy Analysis

Comorbidity	# Events / N		Vaccine Efficacy (95% CI)
	mRNA-1273	Placebo	
Any Comorbidity	**4 / 3,206**	**43 / 3,167**	**90.9%** (74.7, 96.7)
Chronic Lung Disease	**1 / 673**	**9 / 688**	**88.9%** (12.5, 98.6)
Significant Cardiac Disease	**1 / 711**	**6 / 694**	**83.3%** (-38.4, 98.0)
Severe Obesity (>40 kg/m^2)	**2 / 956**	**19 / 936**	**89.9%** (56.8, 97.7)
Diabetes	**1 / 1,364**	**16 / 1,345**	**93.9%** (53.8, 99.2)
Liver Disease	**0 / 95**	**0 / 90**	**NE**
HIV	**0 / 82**	**1 / 77**	**100%**

NE: Not Estimable

Study 301 Secondary Efficacy Endpoint: Cases of Confirmed Severe COVID-19

Per Protocol

Confirmed, Severe COVID-19 Cases	Primary Efficacy Analysis	
	mRNA-1273 N=14,134	Placebo N=14,073
Number of cases, n (%)	0 (0%)	30 (0.2%)
Vaccine efficacy based on hazard ratio (95% CI)	100% (NE, 100%)	
Incidence rate per 1000 person-years	0	9.1

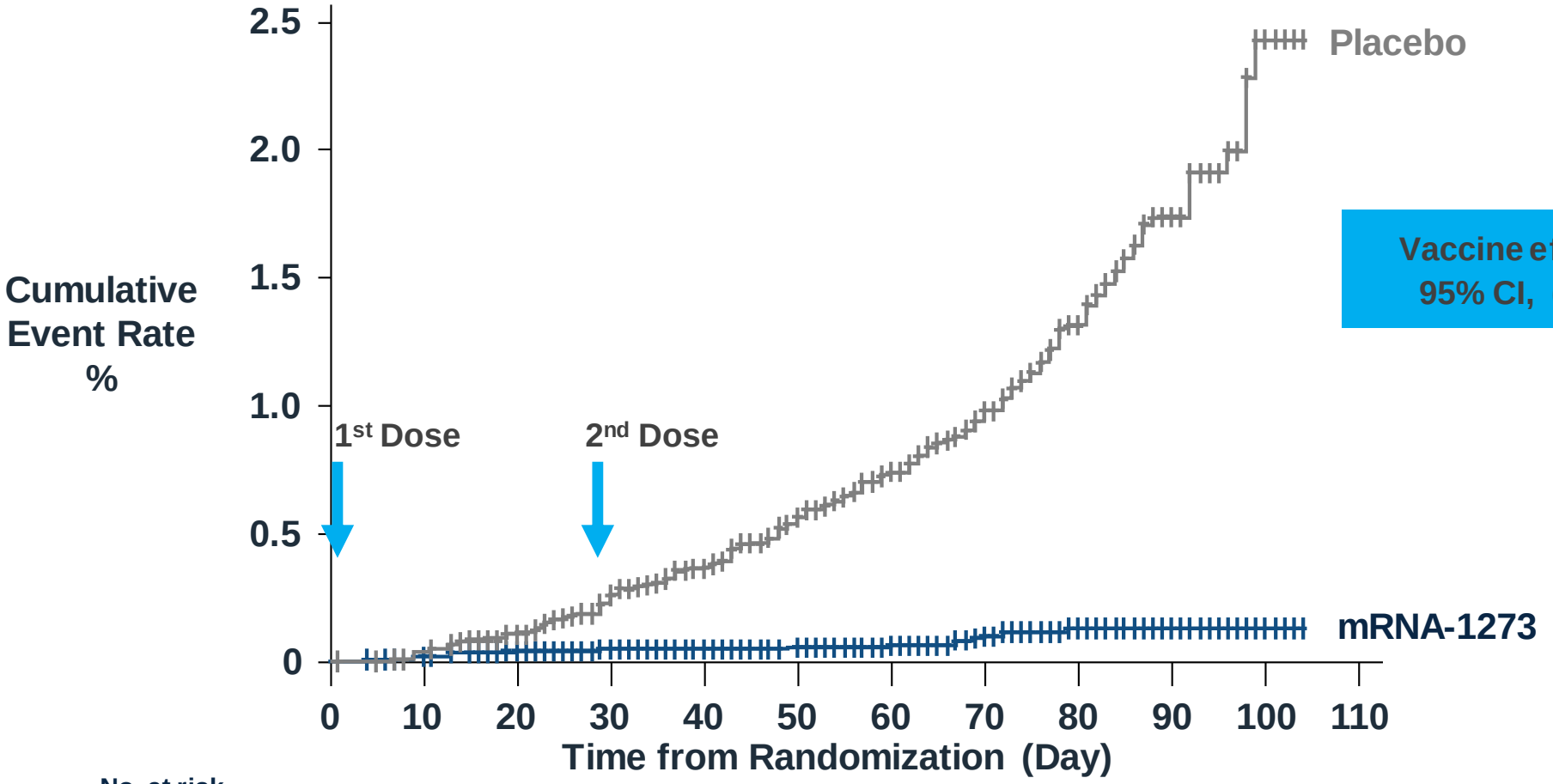
- One participant death due to COVID-19 in the placebo group
- Given the high efficacy against severe disease, no evidence for vaccine-associated enhanced disease was observed

One potential case of severe disease was reported in the mRNA-1273 group after data cut-off for the primary efficacy analysis.

NE: not estimable

Kaplan-Meier Estimates of Time to First Occurrence of COVID-19 Starting After Randomization

mITT – Interim Analysis



Vaccine efficacy = 95.2%
95% CI, (91.2%, 97.4%)

No. at risk												
mRNA-1273	14312	14306	13964	13490	12981	12284	10742	8327	5705	2621	583	0
Placebo	14370	14363	14000	13515	12972	12225	10657	8283	5663	2594	586	0

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Study 301: Post Hoc Analysis of Efficacy of mRNA-1273 14 Days After 1st Injection and After Randomization

mITT Population – Interim Efficacy Analysis

	mRNA-1273 N=996		Placebo N=1,079		
Start of Case Counting	n	%	n	%	VE % (95% CI)
After Randomization	7	0.7%	39	3.6%	80.0% (55.2%, 91.1%)
14 days after Dose 1	2	0.2%	28	2.6%	91.9% (66.1%, 98.1%)

Limitations of analysis:

- **Small, nonrandomized sample of subjects who had not received the second dose**
- **Participants had a median follow-up of 28 days**

Study 301: Summary of COVID-19 Cases Between Randomization and 14 Days After Dose 2 Based on the CDC Case Definition[1]

mITT Population – Interim Analysis

	mRNA-1273 N=14,550 n	Placebo N=14,598 n
From randomization to 14 days post 1st dose	5	11
From 14 days post 1st dose to 2nd dose	3	34
From 2nd dose to 14 days post 2nd dose	0	17
Total	8	62

Data suggest protection may begin prior to dose 2

[1] One clinical symptom from an expanded list and a nasopharyngeal swab positive for SARS-CoV-2 virus

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Study 301: Summary of Asymptomatic SARS-CoV-2 Infections as Measured by Scheduled NP Swabs Prior to 2nd Dose

Per Protocol — Primary Efficacy Analysis

RT-PCR Results and Clinical Symptoms	mRNA-1273 N=14,134		Placebo N=14,073	
	n	%	N	%
Positive RT-PCR and no documented COVID-19 symptoms between 1st dose and 2nd dose	14	0.1%	38	0.3%

Data suggestive of efficacy for prevention of asymptomatic infection

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Study 301: mRNA-1273 100 µg Safety 9-Week Median Follow-up

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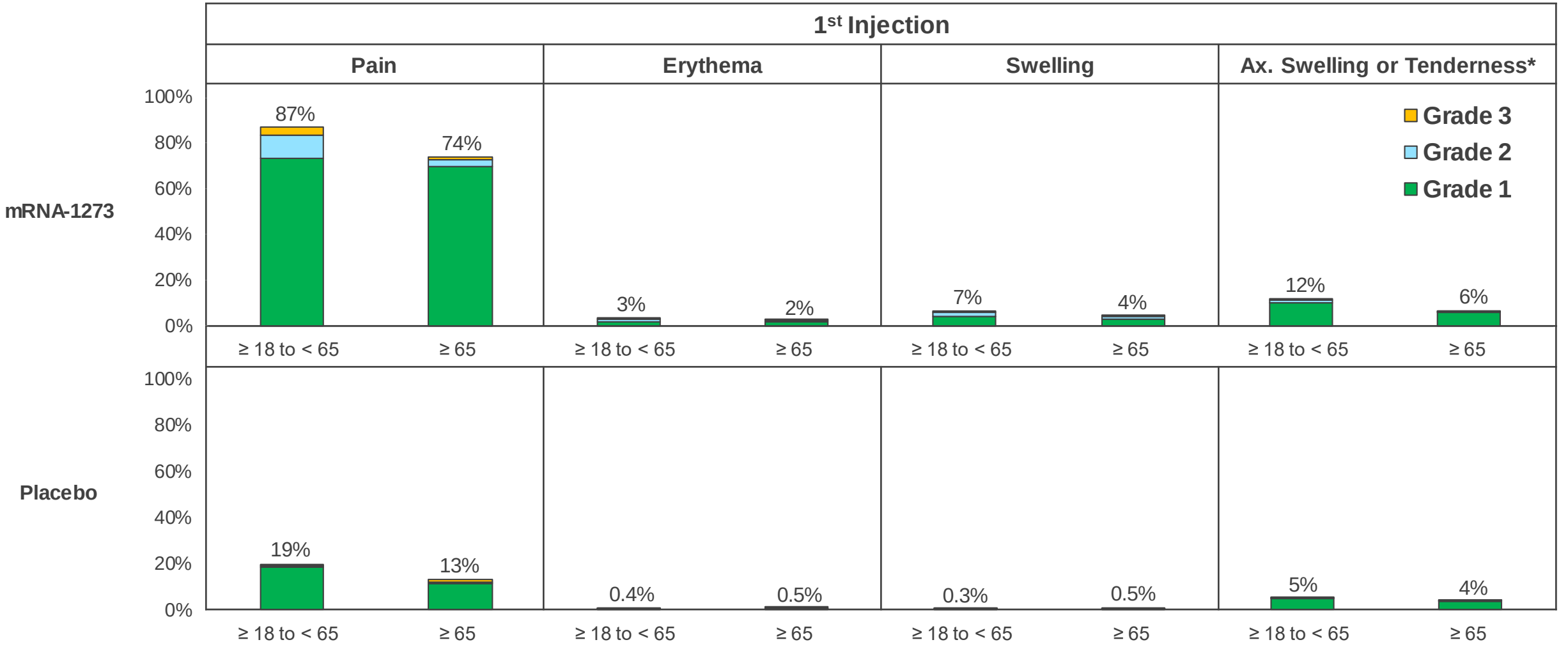
Solicited Adverse Reactions

Study 301 Safety Set (N=30,351)

Study 301: Most Solicited Local Adverse Reactions Were Mild-to-Moderate (1st Injection)

Safety Set, 9-Week Median Follow-up



Note: Includes reports within 7 days of injection. *Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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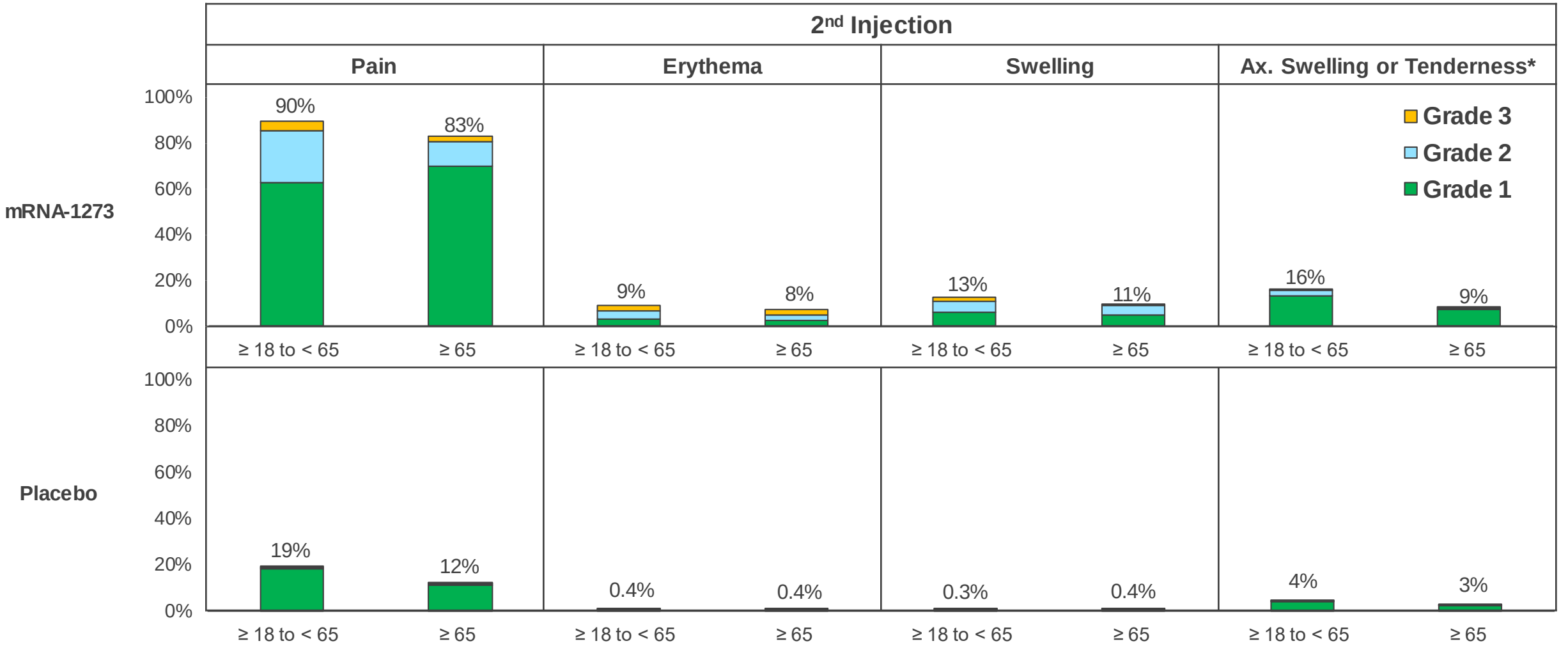
Study 301: Most Solicited Local Adverse Reactions Were Mild-to-Moderate (2nd Injection)

Safety Set, 9-Week Median Follow-up



Note: Includes reports within 7 days of injection. *Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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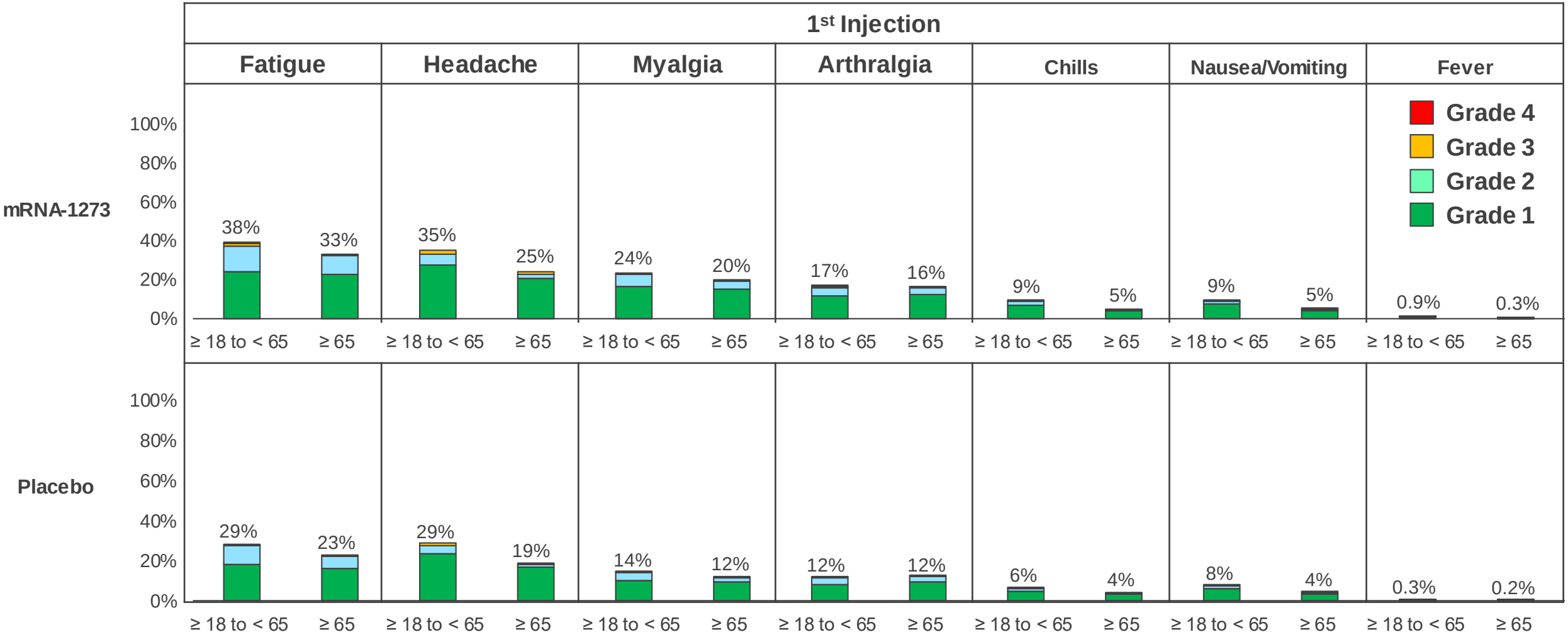
Study 301: Most Solicited Systemic Adverse Reactions Were Mild-to-Moderate (1st Injection)

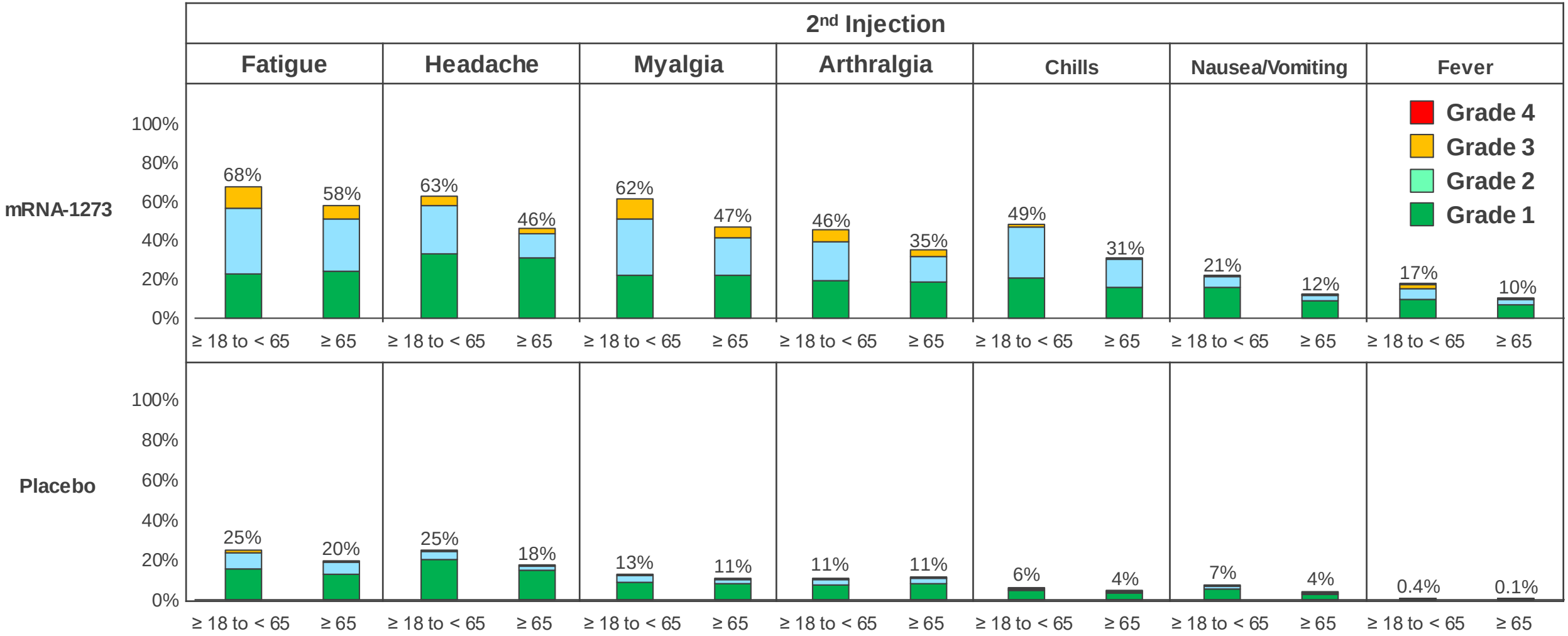
Safety Set, 9-Week Median Follow-up



Note: Solicited Systemic ARs include reports within 7 days of injection
Grade 4 events reported at a rate <0.1%

Study 301: Most Solicited Systemic Adverse Reactions Were Mild-to-Moderate (2nd Injection)

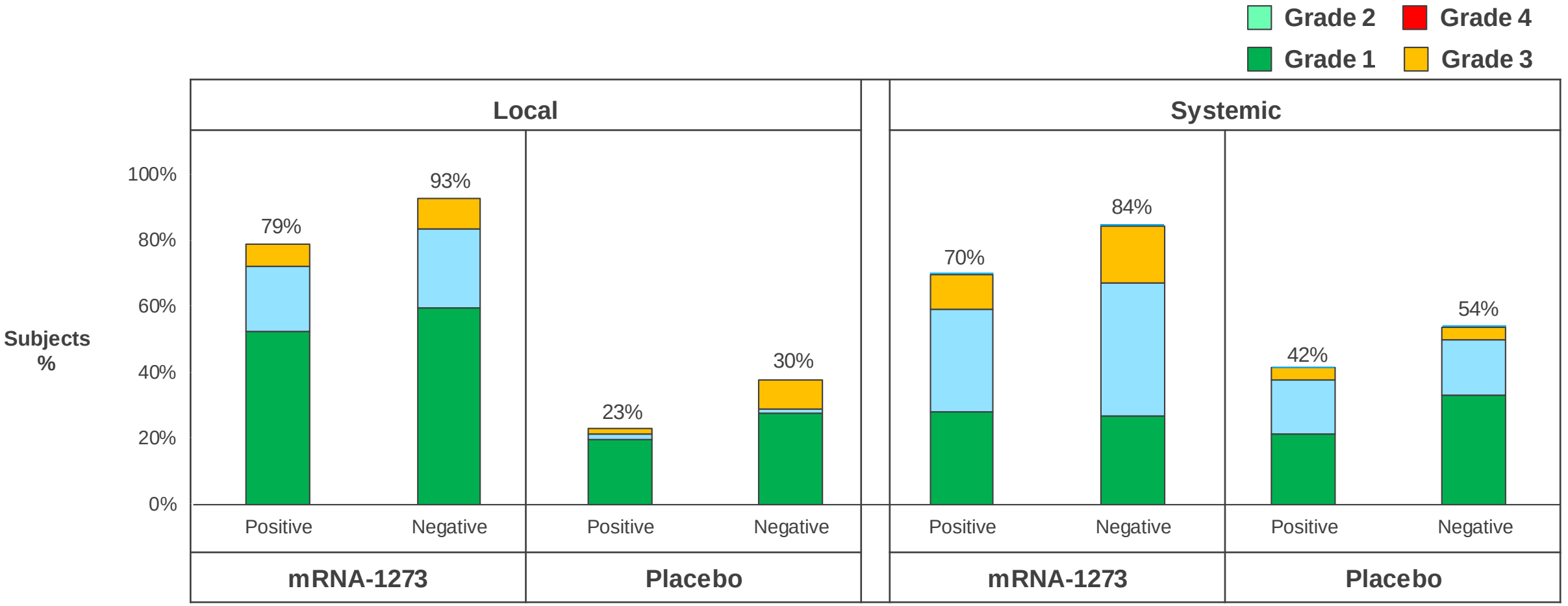
Safety Set, 9-Week Median Follow-up



Note: Solicited Systemic ARs include reports within 7 days of injection
Grade 4 events reported at a rate <0.1%

Study 301: Any Solicited Adverse Reaction by Baseline SARS-CoV-2 Status

Safety Set, 9-Week Median Follow-up



Missing baseline SARS-CoV-2 assessment for 288 mRNA-1273 and 235 Placebo participants
Grade 4 events reported at a rate <0.1%

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Unsolicited Adverse Events

Study 301 Safety Set (N=30,351)

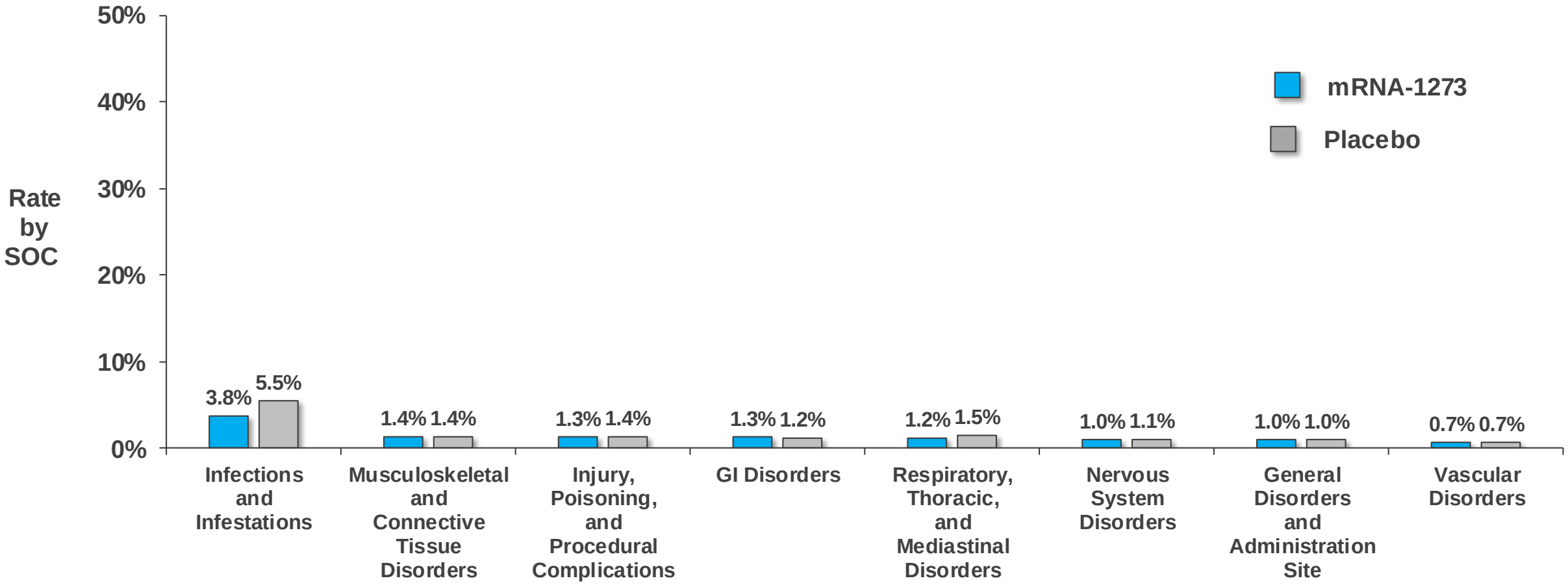
Study 301: Summary of Unsolicited AEs

Safety Set, 9-Week Median Follow-up

Unsolicited Adverse Events	mRNA-1273 N=15,185		Placebo N=15,166	
	n	%	n	%
Any Adverse Event	4,058	**27%**	3,888	**26%**
Any Medically-Attended Adverse Event (MAAE)	1,745	**11%**	1,958	**13%**
Any Serious Adverse Event (SAE)	147	**1%**	153	**1%**
Any death (reported through December 3, 2020)	6	**< 0.1%**	7	**< 0.1%**

Study 301: Rates of Medically-Attended AEs Were Comparable Between Groups

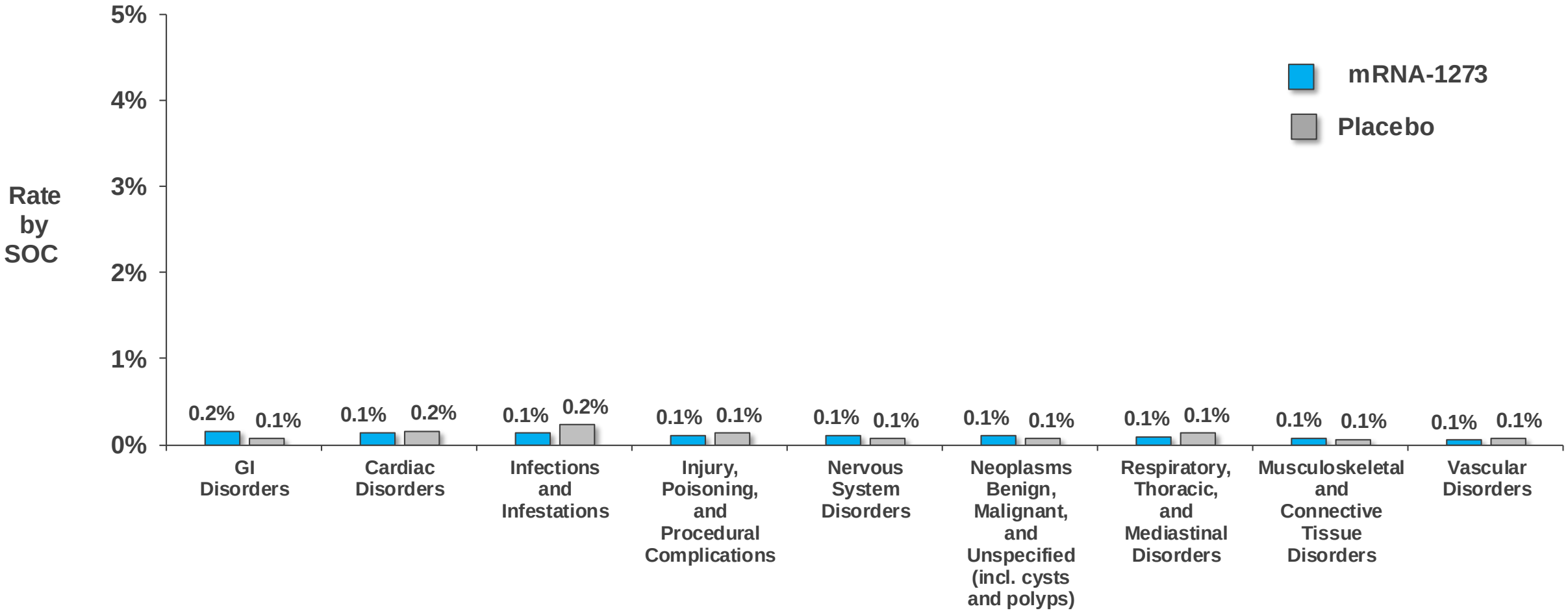
Safety Set, 9-Week Median Follow-up



System Organ Class (SOC) occurring at rate > 0.6%

Study 301: Rates of SAEs Were Comparable Between Groups

Safety Set, 9-Week Median Follow-up



System Organ Class (SOC) occurring at rate > 0.05%

Study 301: Deaths Through December 3, 2020

Preferred Term	mRNA-1273 n=6	Placebo n=7	Relationship to Treatment
Abdominal injury (intra-abdominal perforation)	0	1	Not related
Cardio-respiratory arrest	1	1	Not related
Completed suicide	1	0	Not related
COVID-19	0	1	Not related
Head injury	1	0	Not related
Myocardial infarction	1	2	Not related
Multisystem organ failure	1	0	Not related
Not otherwise specified	1	1	Not related
Systemic inflammatory response syndrome (dermatitis bullous)	0	1	Not related

Cases Suggestive of Anaphylaxis Reported to Moderna: Clinical trial and post-authorization

- No participants excluded for history of anaphylaxis, urticaria, or other significant hypersensitivity
- 2 anaphylactic reactions reported as unsolicited AEs
  - 1 placebo occurring 10 days after 1st dose
  - 1 mRNA-1273 occurring 63 days after 2nd dose
- Conducted anaphylaxis Standardized MedDRA Query (SMQ), including review of events within 48 hours in P3o1
  - 0 met Brighton Collaboration Anaphylaxis Case Definition
- Moderna is aware of one case of anaphylaxis reported post-authorization reported to VAERS post-authorization in the US[1]

[1]MMWR, 15 Jan 2021, 70(2);46-51

Moderna Committed to Collecting Additional Data in a Broader Range of Patients

- Pediatric studies ongoing
- National Cancer Institute collaboration
- Post-authorization active surveillance and safety study
- Global pregnancy registry under development
- Post-authorization effectiveness study under development
- Safety and immunogenicity in transplant patients

Moderna will continue to collaborate with NIH, FDA, CDC and other agencies

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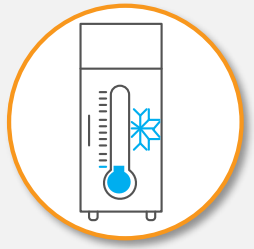
Vaccine Storage & Handling

mRNA-1273 Shipping, Storage and Administration

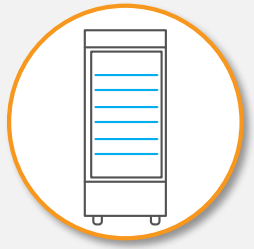
Shipping
-20°C (-40°C to -15°C)

Able to ship a single carton (100 doses)

Local Storage Options
(up to the Date of Expiration)



Freezer
-15 to -25° C



Refrigerator
2 to 8°C
up to 30 days

Room Temperature
up to 12 hours

Local transportation under controlled condition at 2 to 8°C

Administration

Multiple-dose vial

Use within 6 hours after first entry

No dilution required

Summary: Moderna COVID-19 Vaccine Offers Potential to Address the Current Public Health Crisis

- Efficacy
  - 94.1% efficacy demonstrated in primary analysis on 196 cases
  - Primary efficacy hypothesis was met
    - Lower limit of 95% CI was 89.3%, exceeding pre-specified 30% margin
  - Reduced severe COVID-19 disease
    - 0 vs 30 cases in vaccine and placebo groups, respectively
  - Other secondary, sensitivity and subgroup analyses support primary efficacy analysis results
- Safety
  - Acceptable tolerability profile was observed with >96% of subjects having received second dose
    - More solicited events were reported after the second dose
    - Majority of reported solicited adverse events were mild-to-moderate in severity and short-lived in duration
  - Comparable rates of unsolicited adverse events reported between groups
  - Overall safety profile is clinically acceptable
- Vaccine has the potential to address the SARS-CoV-2 pandemic and has been authorized for Emergency Use in US, received Interim Order in Canada, and received authorization in EU, UK, Israel and Switzerland

Thank you to our collaborators, investigators and subjects

P101

- Division of Microbiology and Infectious Diseases, NIAID
- Vaccine Research Center (VRC), NIAID
- Coalition for Epidemic Preparedness Innovation
- Principal Investigators, Drs. Lisa Jackson (Kaiser Permanente Washington), Evan Anderson (Emory University School of Medicine), Nadine Rouphael (Emory University School of Medicine), Alicia Widge (VRC)
- The Emmes Company
- Denison Lab, Vanderbilt University
- Baric Lab, University of North Carolina
- Suthar Lab, Emory University
- Vaccine Immunology Program, NIAID
- Study sites, investigators and subjects

P201

- BARDA
- Study sites, investigators, and subjects

COVE Study (P301)

- BARDA
- Operation Warp Speed
- NIAID and the COVID-19 Prevention Network
- Members of Diversity and Inclusion Panel
- Principal Investigators, Drs. Brandon Essink (Meridian Clinical Research), Lindsey Baden (Brigham and Women's Hospital), Hana El Sahly (Baylor College of Medicine)
- Study sites, investigators, and subjects

Back-Up

Study 301: Participants with Occupational Risk Factors

Full Analysis Set — Primary Efficacy Analysis

	mRNA-1273 N=15,181		Placebo N=15,170	
	n	%	n	%
Healthcare workers	3,790	**25%**	3,831	**25%**
Educators and students	1,543	**10%**	1,552	**10%**
Pastoral, social, or public health workers	533	**4%**	503	**3%**
Transportation and delivery services	482	**3%**	473	**3%**
Personal care and in-home services	469	**3%**	469	**3%**
Manufacturing and production operations	425	**3%**	421	**3%**
Emergency response	302	**2%**	297	**2%**
Warehouse shipping and fulfillment centers	191	**1%**	175	**1%**
Border protection and military personnel	69	**0.5%**	68	**0.4%**

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