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

ACIP – December 20, 2020

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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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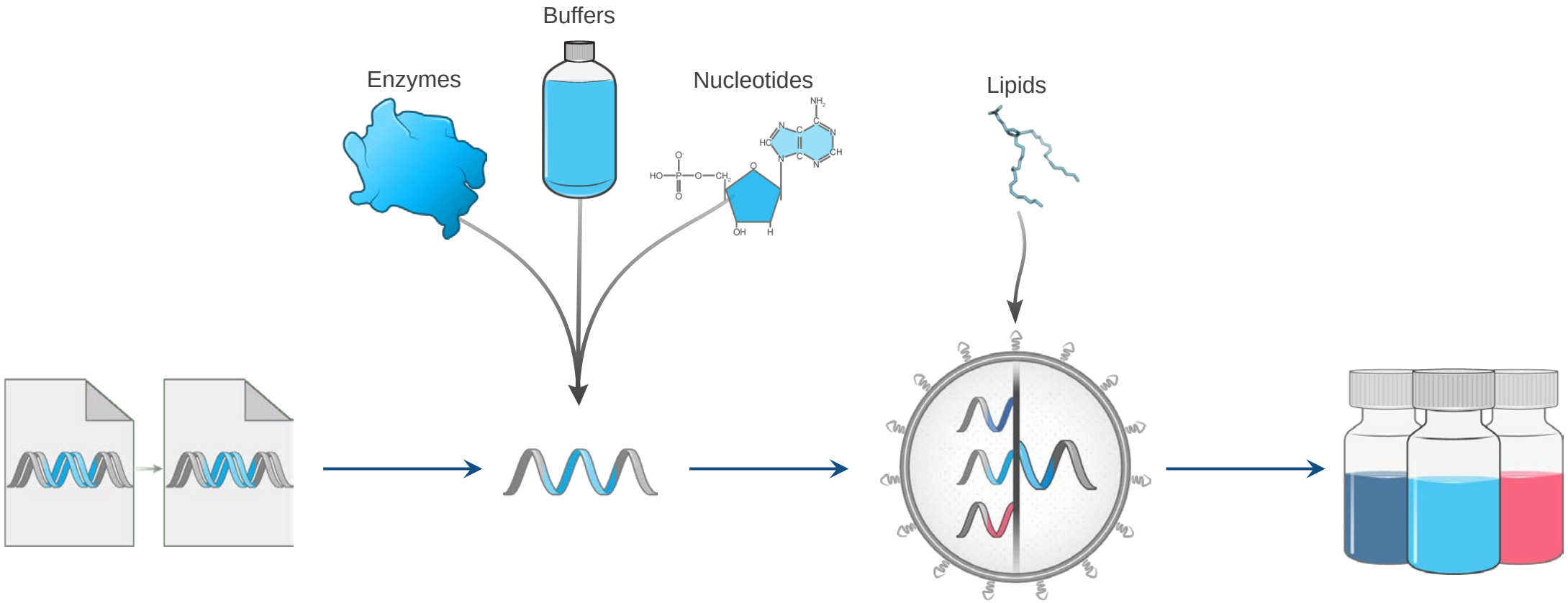
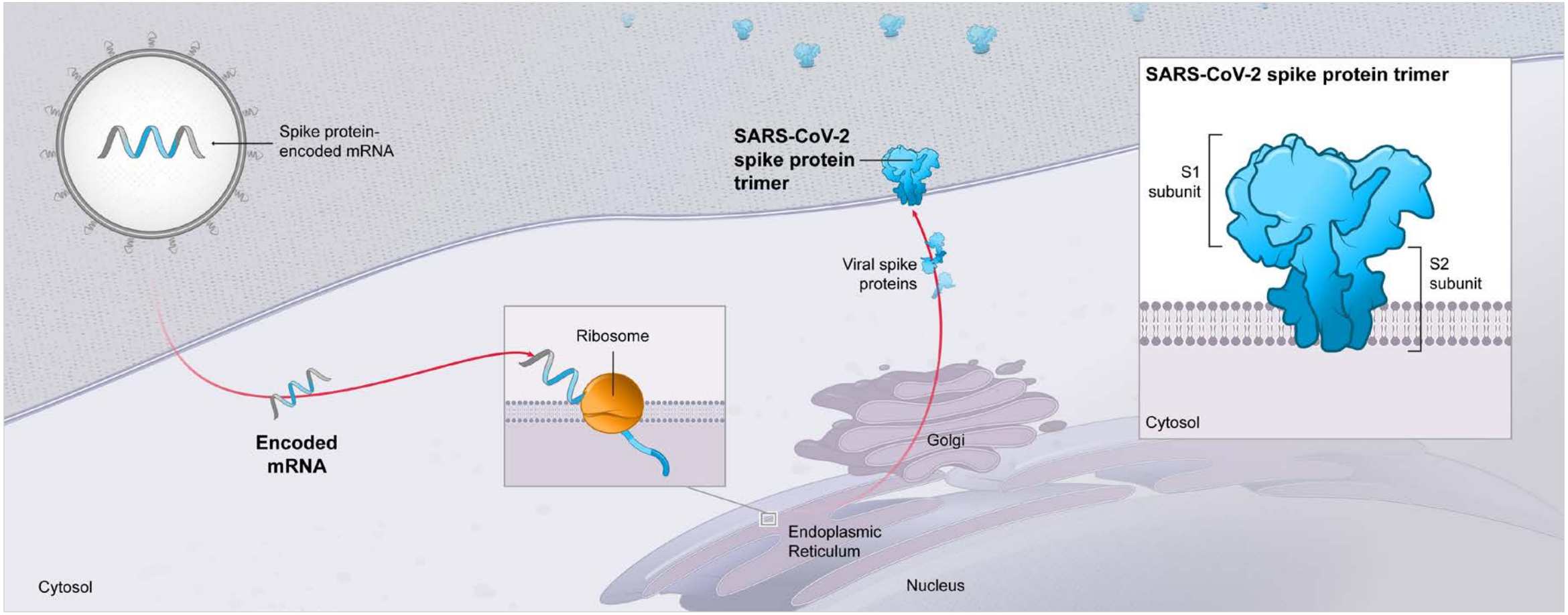
mRNA Platform

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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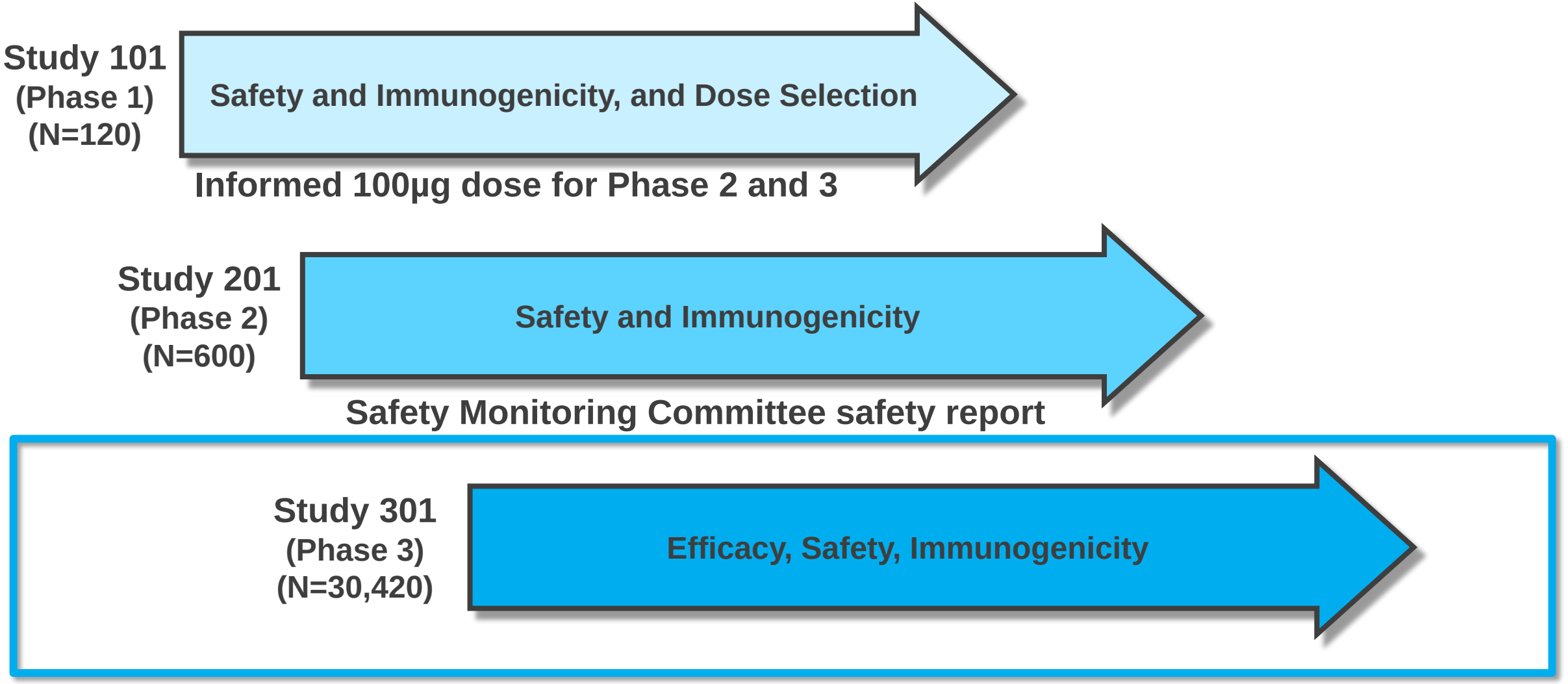
mRNA-1273 Preclinical & Clinical Programs

mRNA-1273 Non-clinical Results

- Immunogenic
  - Drives robust SARS-CoV-2 specific 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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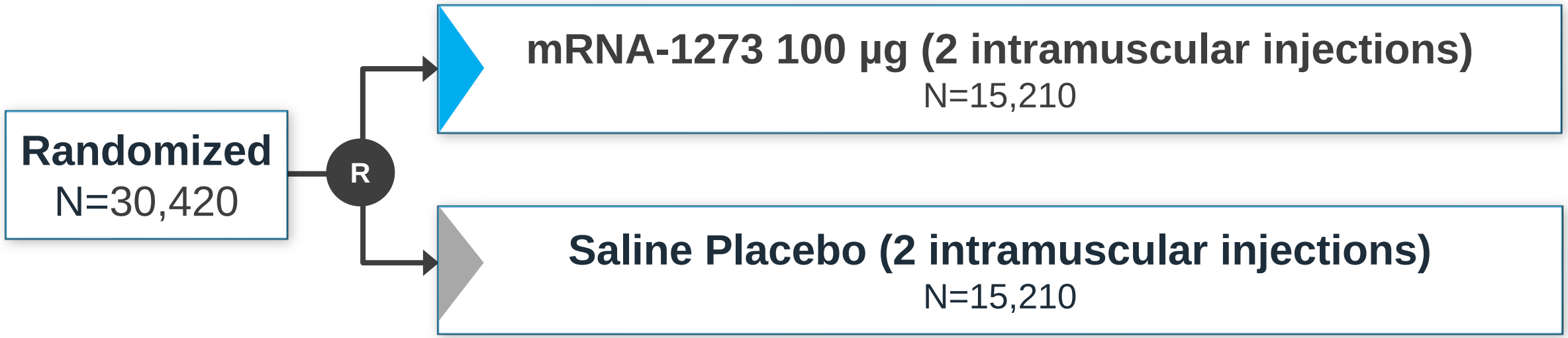
Summary of Studies 101 and 201 mRNA-1273 Immunogenicity Data

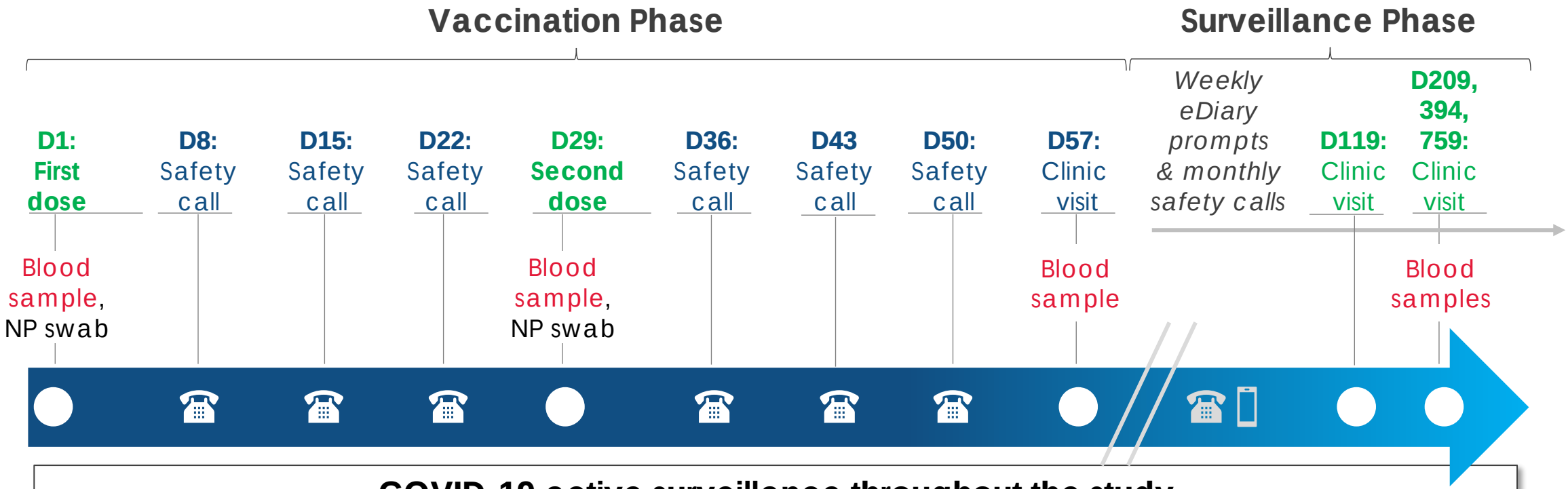
- Neutralizing antibody titers observed in all participants following 2nd dose
- GMTs across age strata numerically higher than in pool of convalescent sera
- Neutralizing antibodies persisted for at least 3 months after 2nd dose and remained numerically higher than convalescent sera
- Strong Th-1 dominant,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

Study 301 – Large Scale 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 any one 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

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: Participants with Occupational Risk Factors Under Consideration for Priority Vaccination

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

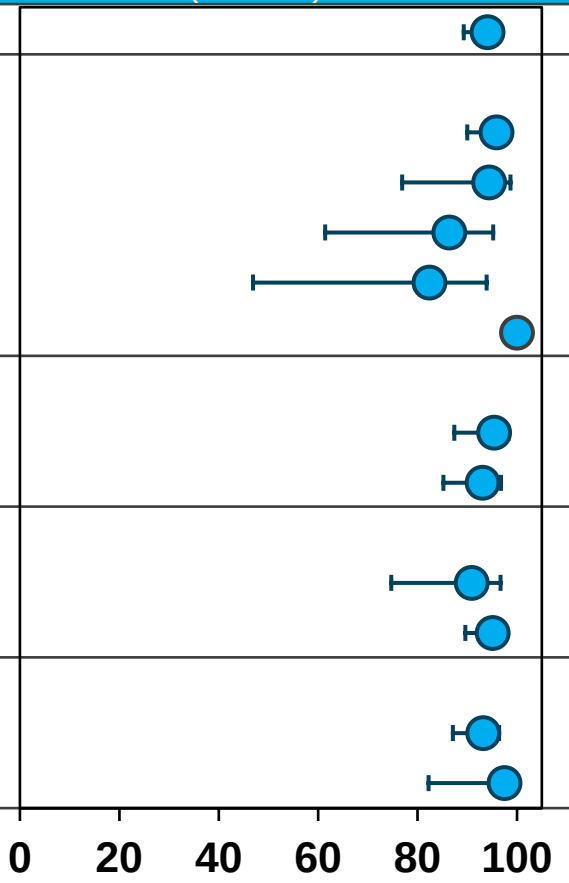
Per Protocol

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 < 70 with or without comorbidities	**4 / 2,953**	**22 / 2,864**		**82.4%** (46.9%, 93.9%)
≥ 70 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 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

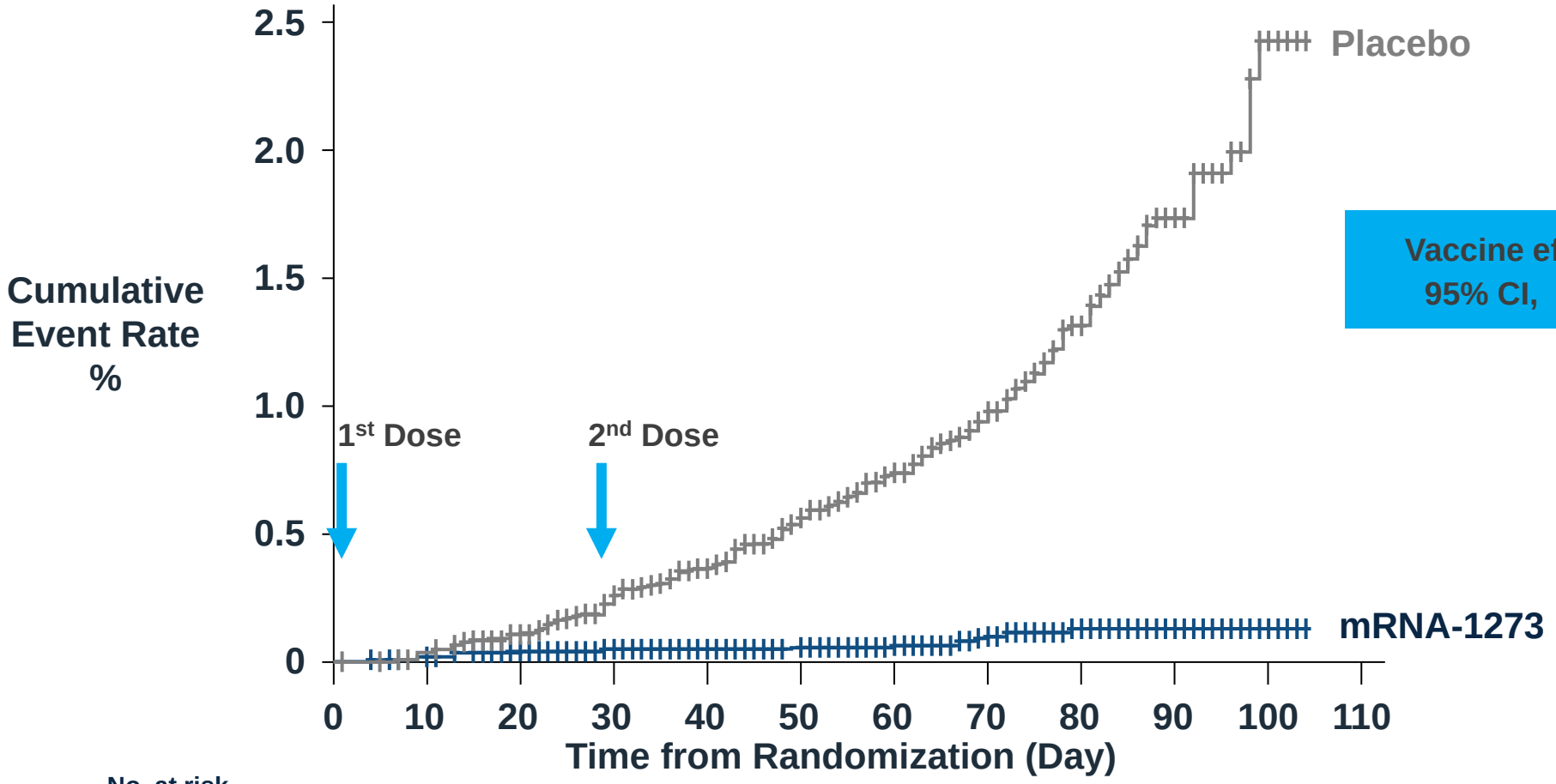
- One participant death due to COVID-19 in the placebo group
- Given the high efficacy against severe disease, no evidence for vaccine-associated enhanced disease was observed

One potential case of severe disease was reported in the mRNA-1273 group after data cut-off for the primary efficacy analysis, this case has yet to be adjudicated.

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: Summary of COVID-19 Cases Within 6 Weeks After Randomization Based on 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

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 NP Swab Results	mRNA-1273 N=14,134		Placebo N=14,073	
	n	%	N	%
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

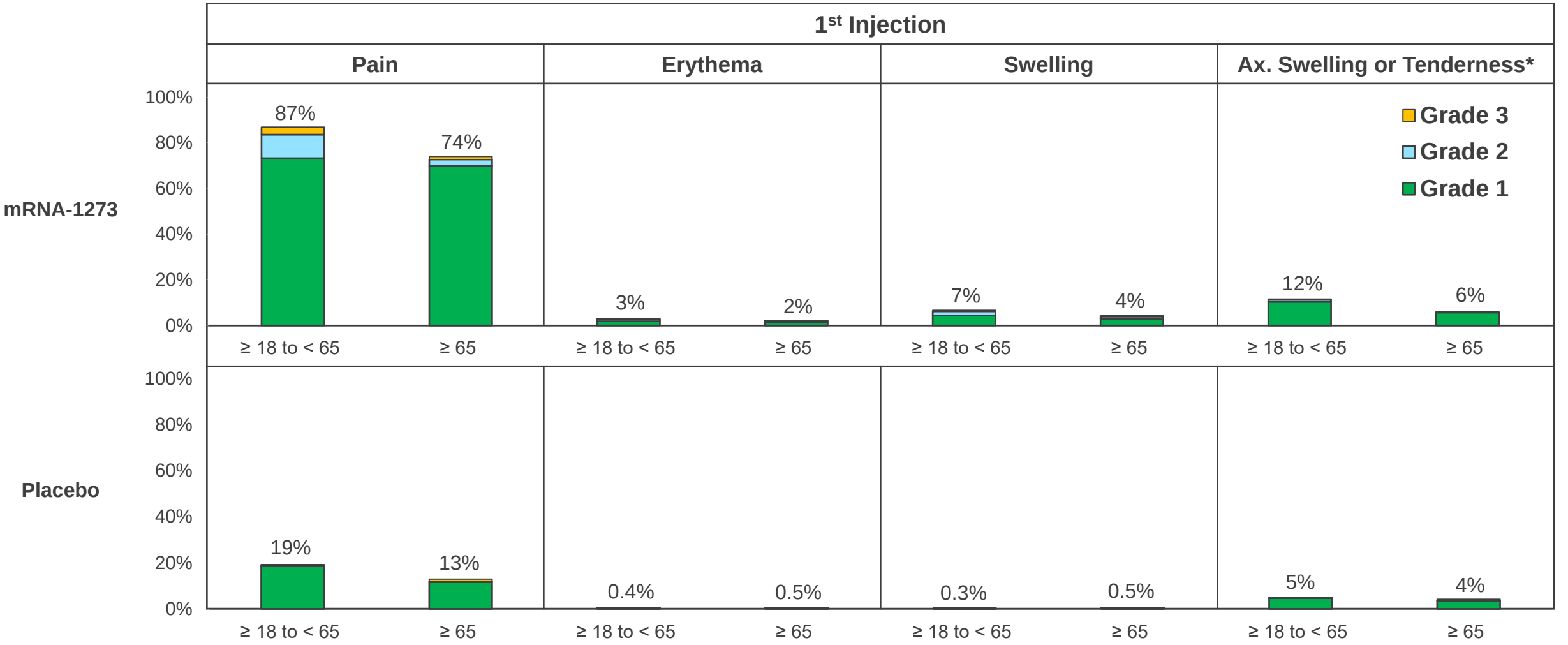
Study 301: mRNA-1273 100 µg Safety 9-Week Median Follow-up

Solicited Adverse Reactions

Study 301 Safety Set (N=30,351)

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

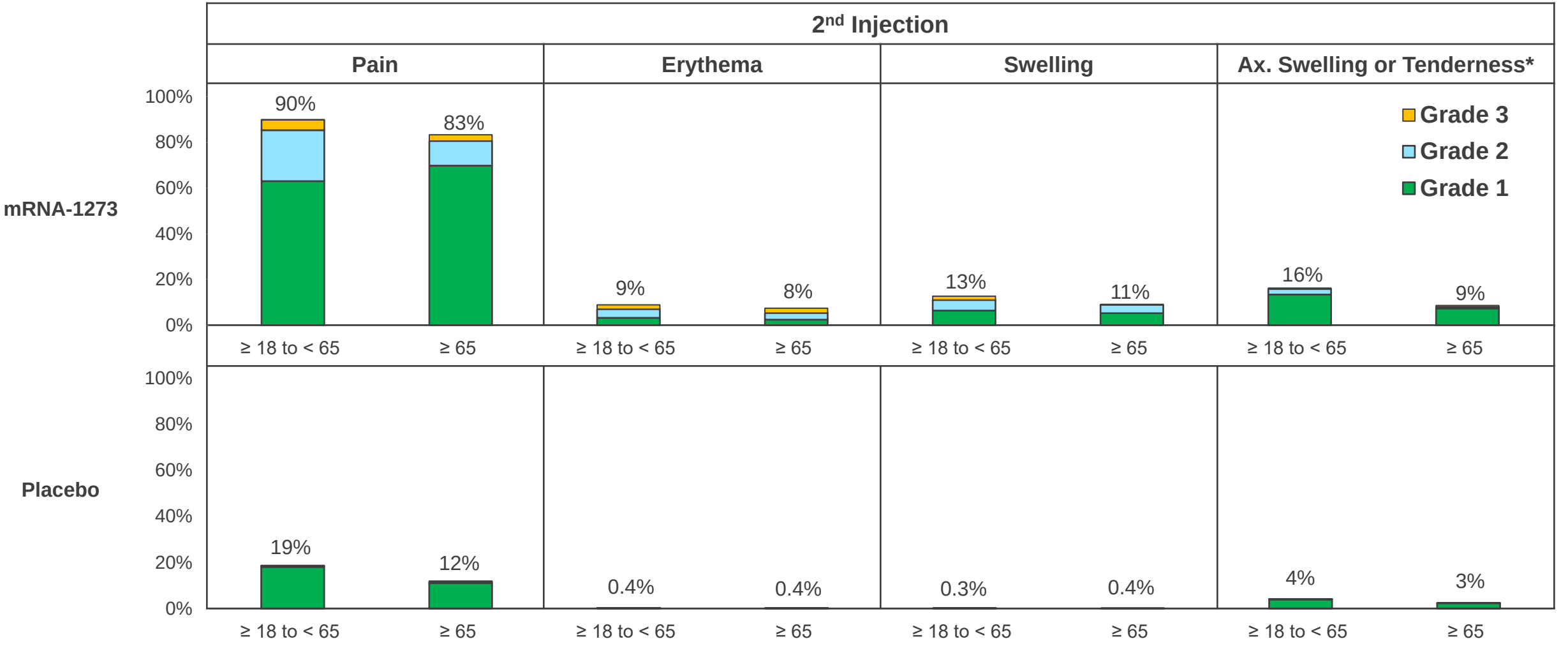
Safety Set, 9-Week Median Follow-up



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

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

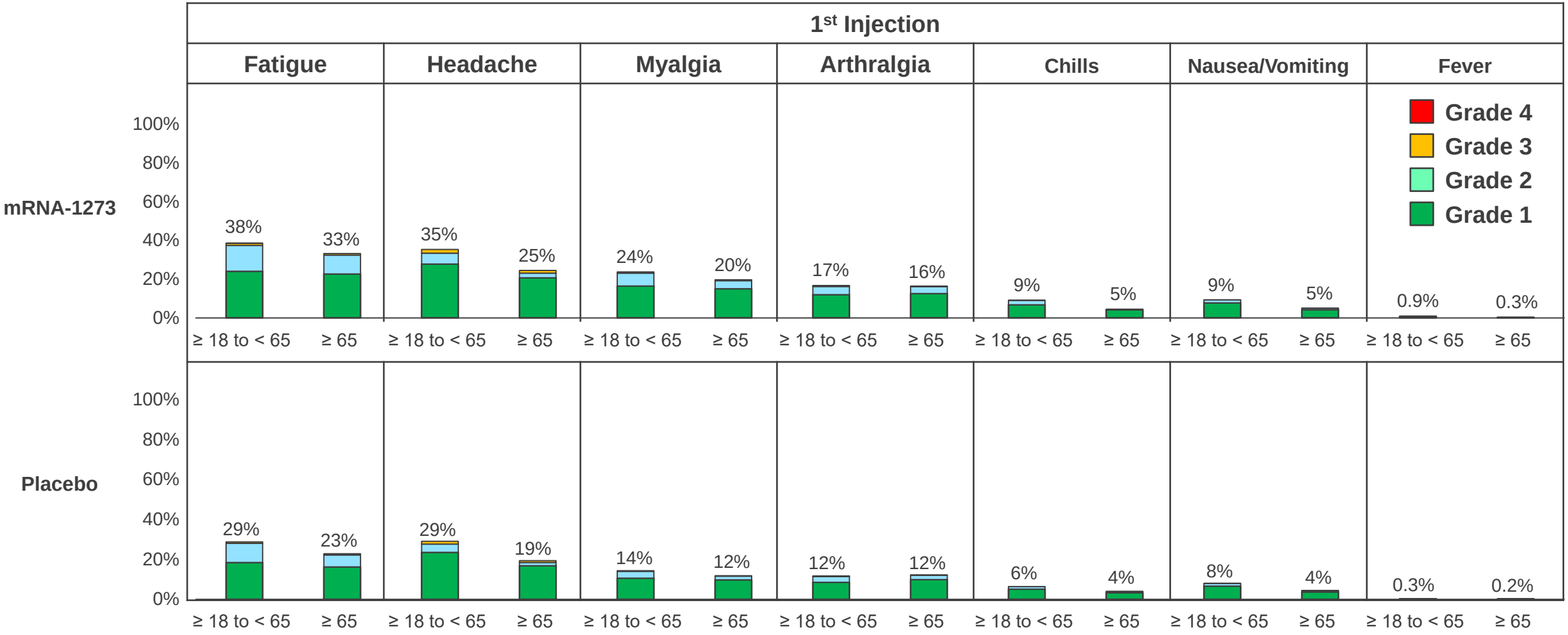
Safety Set, 9-Week Median Follow-up



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

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

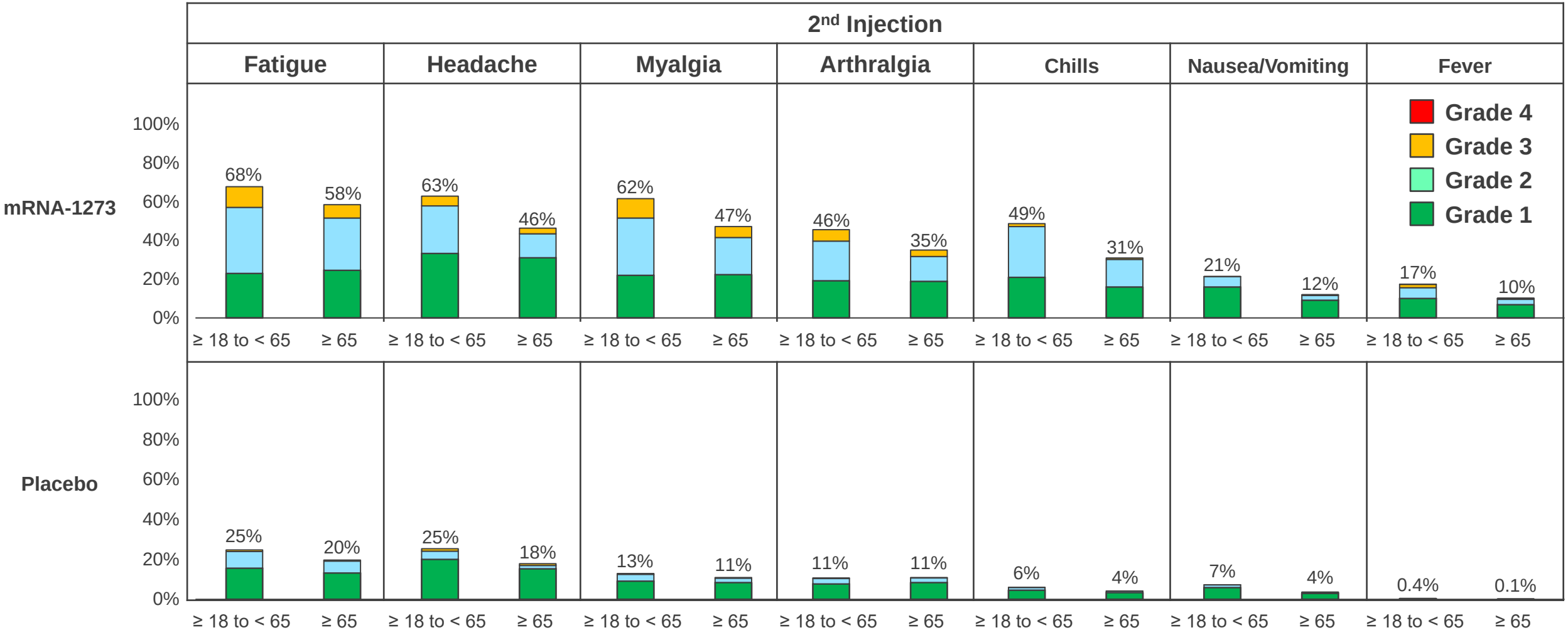
Safety Set, 9-Week Median Follow-up



Note: Solicited Systemic ARs include reports within 7 days of injection

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

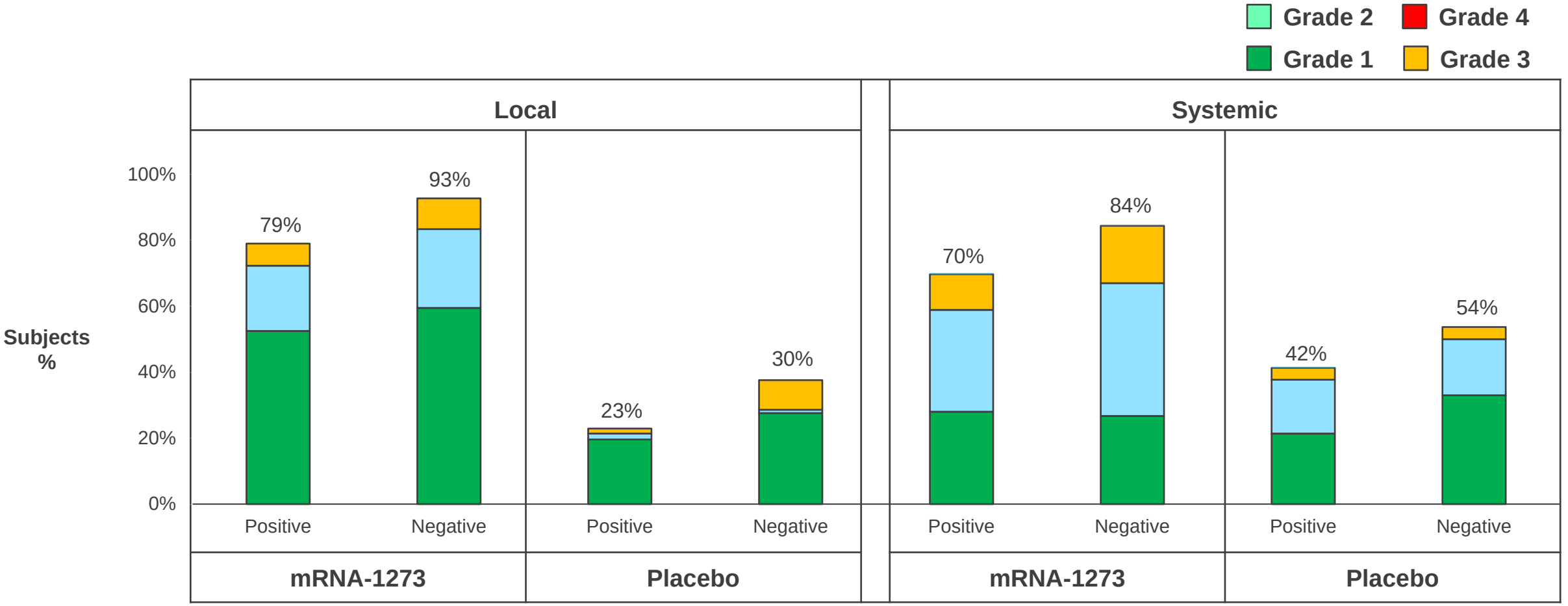
Safety Set, 9-Week Median Follow-up



Note: Solicited Systemic ARs include reports within 7 days of injection

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

Unsolicited Adverse Events

Study 301 Safety Set (N=30,351)

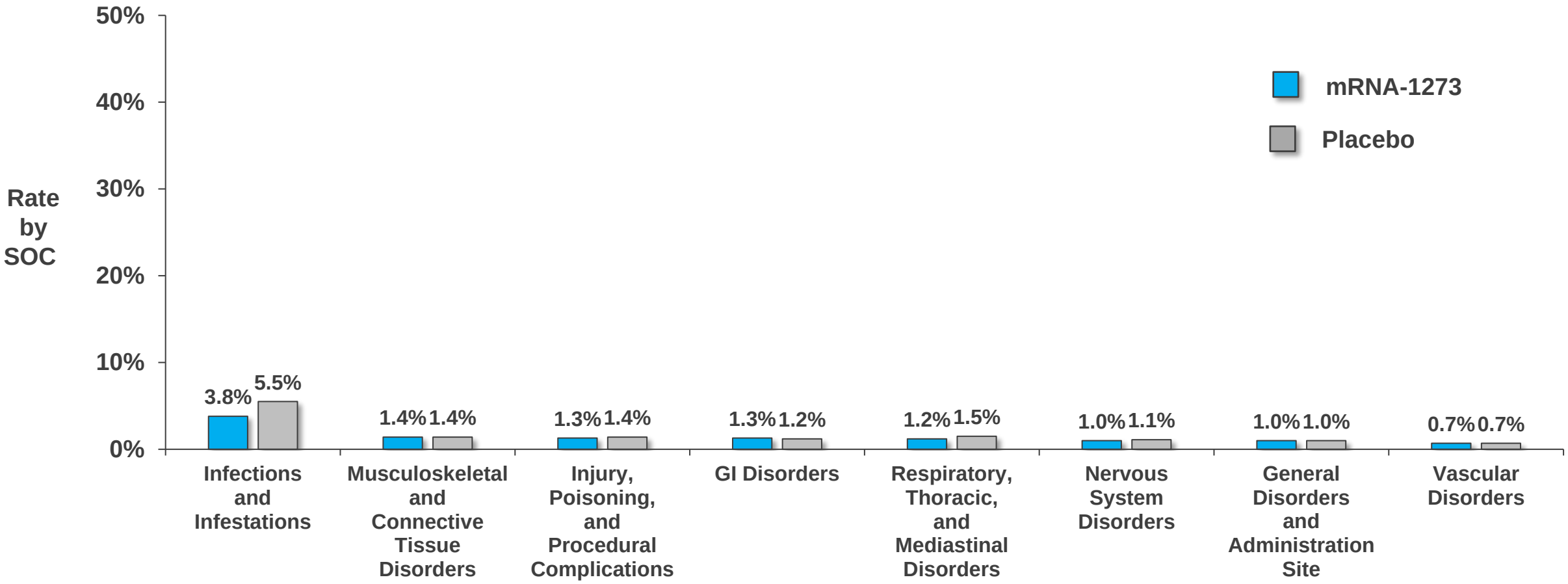
Study 301: Summary of Unsolicited AEs

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

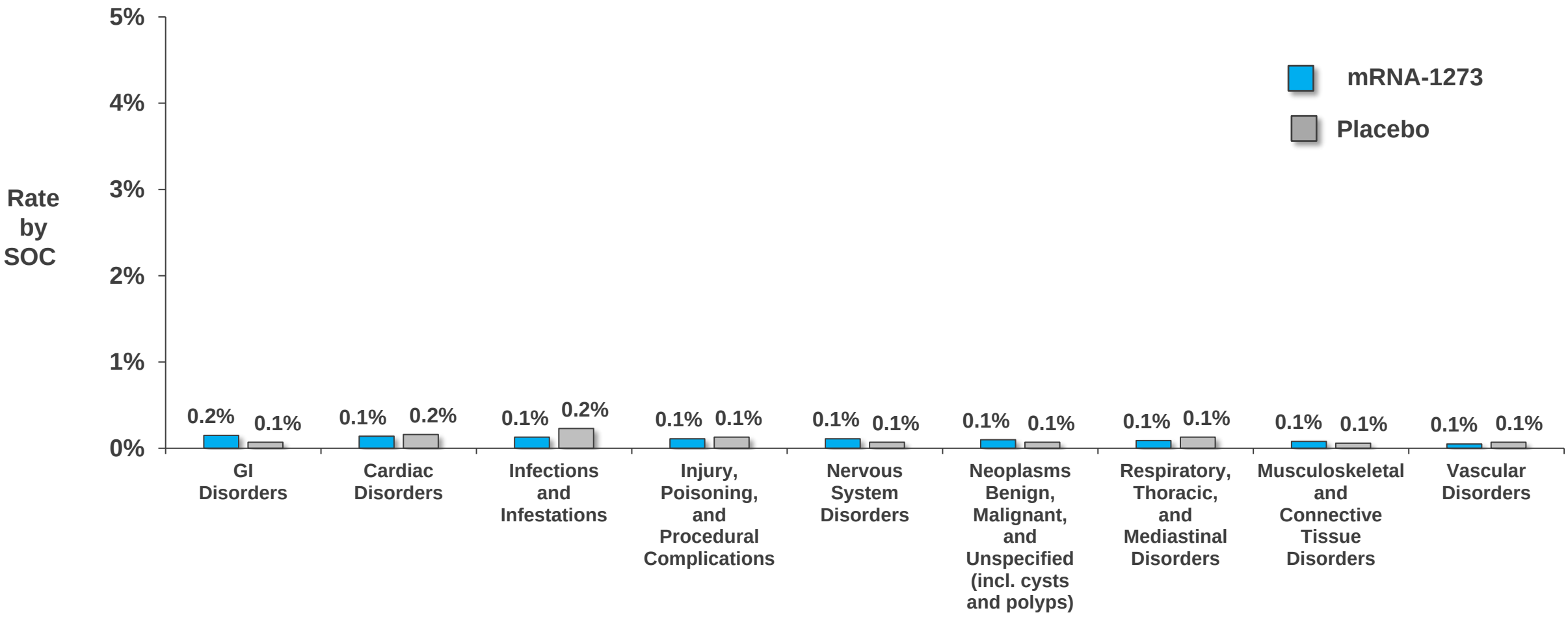
Safety Set, 9-Week Median Follow-up



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

Investigations Unable to Identify Cases Suggestive of Anaphylaxis Associated with mRNA-1273

- 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
  - 0 met Brighton Collaboration Anaphylaxis Case Definition

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

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

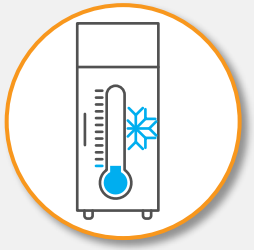
Vaccine Storage & Handling

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: mRNA-1273 Offers Potential to Address the Public Health Crisis of COVID-19

- 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
  - Overall safety profile is clinically acceptable
- Vaccine has the potential to address the SARS-CoV-2 pandemic and has been authorized for Emergency Use

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