Vaccines and Related Biological Products Advisory Committee Meeting

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Emergency Use Authorization (EUA) Application for NVX-CoV2373

Novavax, Inc.

Vaccines and Related Biological Products Advisory Committee

June 7, 2022

Emergency Use Authorization (EUA) Application for NVX-CoV2373

Filip Dubovsky, MD, MPH, FAAP

Executive Vice President & Chief Medical Officer

Novavax, Inc.

NVX-CoV2373: Well-Defined Vaccine Platform

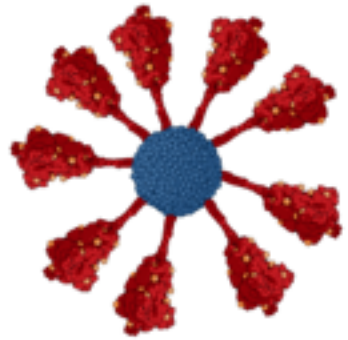
Recombinant protein vaccine,
naturally derived adjuvant

Robust immunogenicity, high levels of efficacy against
mild, moderate, severe COVID-19

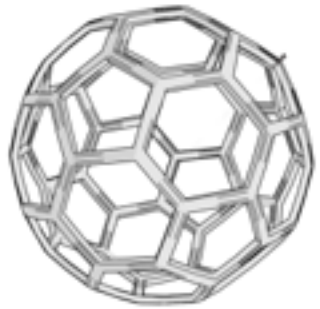
Favorable reactogenicity and positive benefit-risk profile
in large, diverse patient population

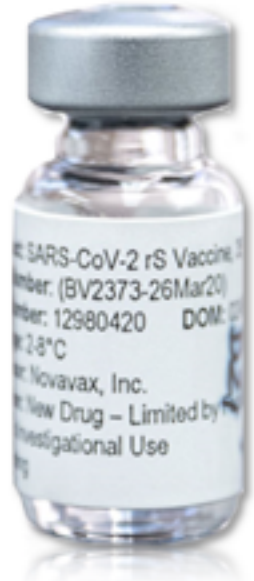
Novavax Vaccine Platform
Recombinant Protein Plus Matrix-M™

Recombinant protein



Matrix-M adjuvant





Novavax vaccine platform

Recombinant Proteins Represent a Well-Understood Vaccine Platform

- Approved recombinant protein vaccines
  - Influenza
  - Hepatitis
  - Human Papillomavirus (HPV)
  - Meningococcal B (MenB)
  - Shingles
- Approved vaccines including saponin-based adjuvants
  - Malaria
  - Shingles

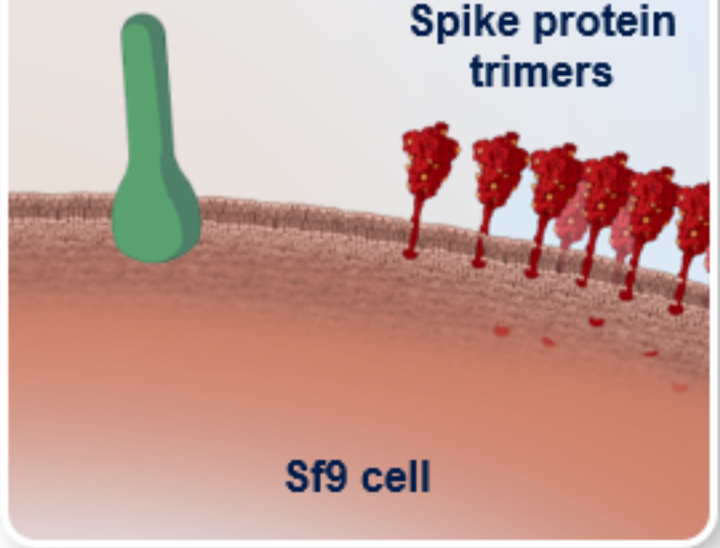
NVX-CoV2373 Antigen Full-Length Recombinant Spike Protein

1 SARS-CoV-2 spike gene inserted into insect virus

Baculovirus

Modified spike protein gene

2 Sf9 insect cell expressed protein trimers



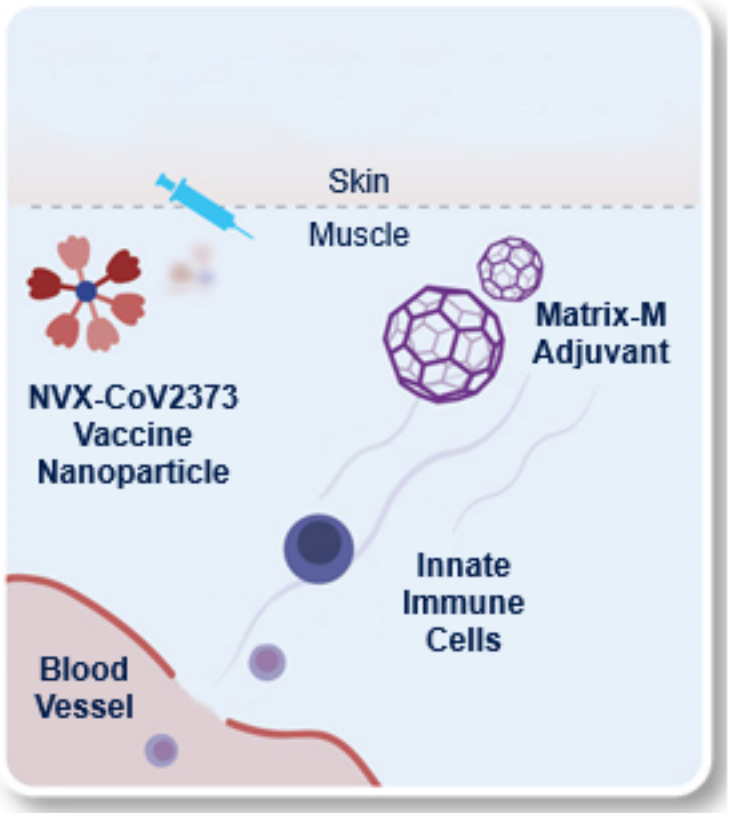
3 Vaccine formation

Matrix-M adjuvant

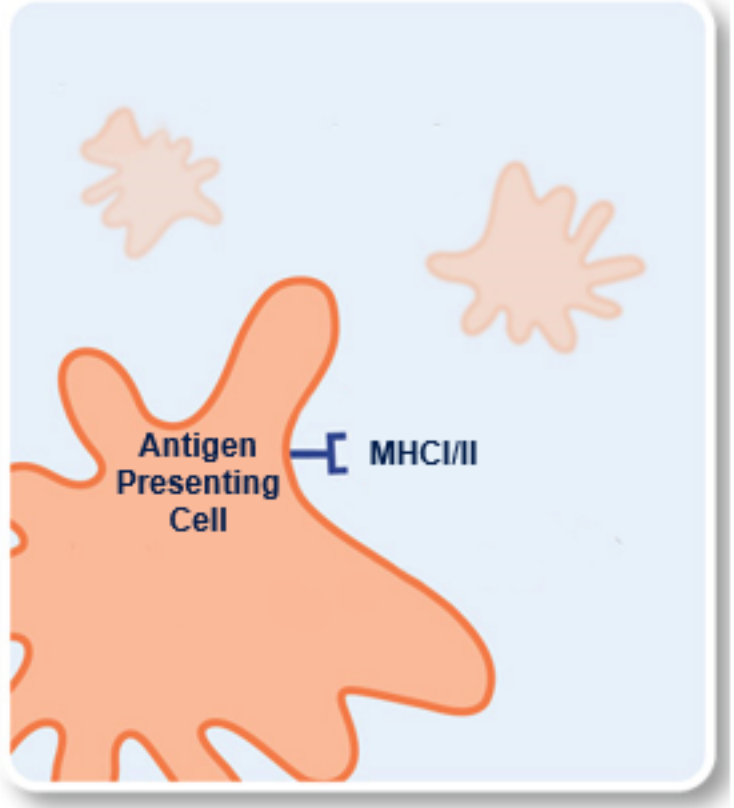
Polysorbate core

Matrix-M Increases Magnitude and Breadth of Immune Response

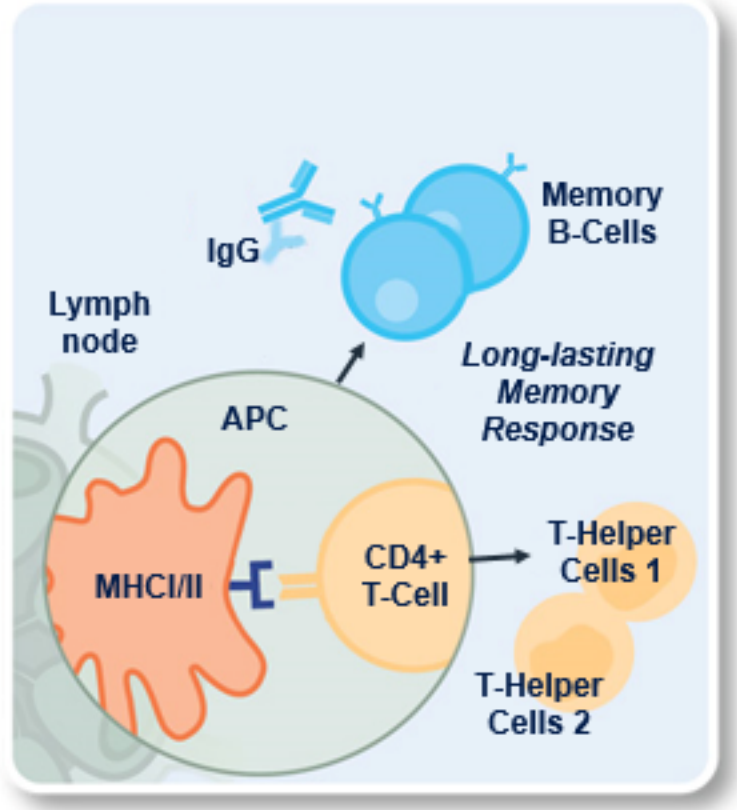
Recruitment and transient activation of innate immune cells



Rapid antigen delivery to and activation of antigen-presenting cells



Enhanced antigen presentation by MHC I and MHC II molecules in draining lymph nodes



NVX-CoV2373 Vaccine Presentation and Storage Supports Access and Ease of Use

Presentation

- 10-dose vials
- Preservative-free

Transportation & Storage

- Stable at 2 to 8°C

Dose Level & Regimen

- 5 µg antigen + 50 µg Matrix-M
- 2 doses given at least 21 days apart
- 0.5 mL intramuscular injection

Initial Indication

- ≥ 18 years of age

NVX-CoV2373 Robust Clinical Development Program

PHASE 1-2
Study 101 (US/AU)

N = 131 (Ph. 1)
N = 1,288 (Ph. 2)

Keech et al., NEJM, 2020; Formica et al., PLoS Medicine, 2021

- Established dose level in younger and older adults
- Confirmed need for adjuvant and 2 dose schedule
- Defined immunologic phenotype
- Assessed preliminary safety profile

PHASE 2a/b
Study 501 (ZA)

N = 4,419

Shinde et al., NEJM, 2021

- Evaluated preliminary efficacy
- Defined safety profile
- Included participants with HIV

PHASE 3
Study 302 (UK)

N = 15,187

Heath et al., NEJM, 2021; Toback et al., The Lancet Res Med, 2021

- Established safety profile
- Established efficacy
- Evaluated safety with influenza vaccine

PHASE 3
Study 301 (US/MX)

Adults
N = 29,945

12 to < 18 years
N = 2,247

Dunkle et al., NEJM, 2021

- Established safety profile in US population
- Established efficacy in US population

High Levels of Protection Achieved with NVX-CoV2373

Overall Efficacy	90.4%
Medical Comorbidities	92%
Against Moderate and Severe Disease	100%
Matched Strain	97% Non-Variants of Interest / Concern
Against Variants	94% Alpha (B.1.1.7) 93% All VoI / VoC

VoI = variants of interest; VoC = variants of concern

Circulating Variants During Study 301 (US/MX)

	Study 301 (US/MX)
Variants of Concern (VoC)	**Alpha** (B.1.1.7) **Beta** (B.1.351) **Epsilon** (B.1.427/429) **Gamma** (P.1)
Variants of Interest (VoI)	**Delta** (B.1.617.2) **Iota** (B.1.526) **Kappa** (B.1.617.1) **Zeta** (P.2)
Non-variants	**Original** (Wuhan-like) / D614G

NVX-CoV2373 Authorizations


World Health Organization


European Union


UK


India*


Switzerland


Japan†


South Korea


United Arab Emirates


Bangladesh


Australia


The Philippines


Thailand*


Canada


New Zealand


Indonesia


Singapore

*Approved for adolescents; †Approved for booster

Status of Ongoing Clinical Development Program

- Study 301 adolescent results submitted to FDA for review
- Completion of safety follow-up from Phase 2-3 studies
- Continuation of pediatric evaluation
  - Adolescents (boosting)
  - School-age children and younger
- Clinical evaluation of variant vaccines for circulating SARS-CoV-2 variants
- Evaluation of homologous and heterologous boosting
- Post-authorization studies for effectiveness and safety monitoring

Agenda

Immunogenicity and Efficacy	**Raburn Mallory, MD** Senior Vice President & Head of Clinical Development Novavax, Inc.
Safety	**Denny Kim, MD, MPH** Senior Vice President & Chief Safety Officer Head of Global Vaccine Safety Novavax, Inc.
Clinical Perspective	**Gregory A. Poland, MD, FIDSA, MACP, FRCP** Mary Lowell Leary Emeritus Professor of Medicine Distinguished Investigator of the Mayo Clinic Director, Mayo Vaccine Research Group
Conclusion	**Filip Dubovsky, MD, MPH, FAAP** Executive Vice President & Chief Medical Officer Novavax, Inc.

Additional Responders

Mori Krantz, MD, FACP, FACC
Governor, American College of Cardiology (Colorado Chapter)
Senior Cardiologist, Clario Inc.

Greg Glenn, MD
President, R & D
Novavax, Inc.

Henrietta Ukwu, MD, FACP
SVP, Chief Regulatory Officer
Novavax, Inc.

Marco Cacciuttolo, PhD
SVP, Process & Analytical Dev.
Novavax, Inc.

Iksung Cho, MS
VP, Biostatistics
Novavax, Inc.

Nita Patel, MS
VP, Vaccine Immunology
Novavax, Inc.

Rick Crowley, MS
EVP, COO
Novavax, Inc.

Lisa Dunkle, MD
VP, Global Medical Lead, Study 301
Novavax, Inc.

Immunogenicity and Efficacy

Raburn Mallory, MD

Senior Vice President & Head of Clinical Development

Novavax, Inc.

NVX-CoV2373 Demonstrated High Levels of Immunogenicity and Efficacy

- Induced high levels of neutralizing antibodies in both younger and older adults
- Showed high levels of efficacy in preventing COVID-19
- High level of efficacy for Variants of Concern / Variants of Interest
- Provided complete protection from moderate and severe COVID-19

NVX-CoV2373 Non-Clinical Results Supported Progressing to Clinical Development

Types of studies	Key findings
Immunogenicity	▪ Induced anti-spike IgG, hACE2-binding inhibiting antibodies, and neutralizing antibodies ▪ Induced strong Th1-type CD4+ T-cell responses[1]
Animal challenge	▪ Suppressed viral replication in both upper and lower airways ▪ No evidence of enhanced disease pathology
Toxicology	▪ No safety concerns identified in standard toxicology program ▪ No adverse findings in developmental and reproductive toxicology study

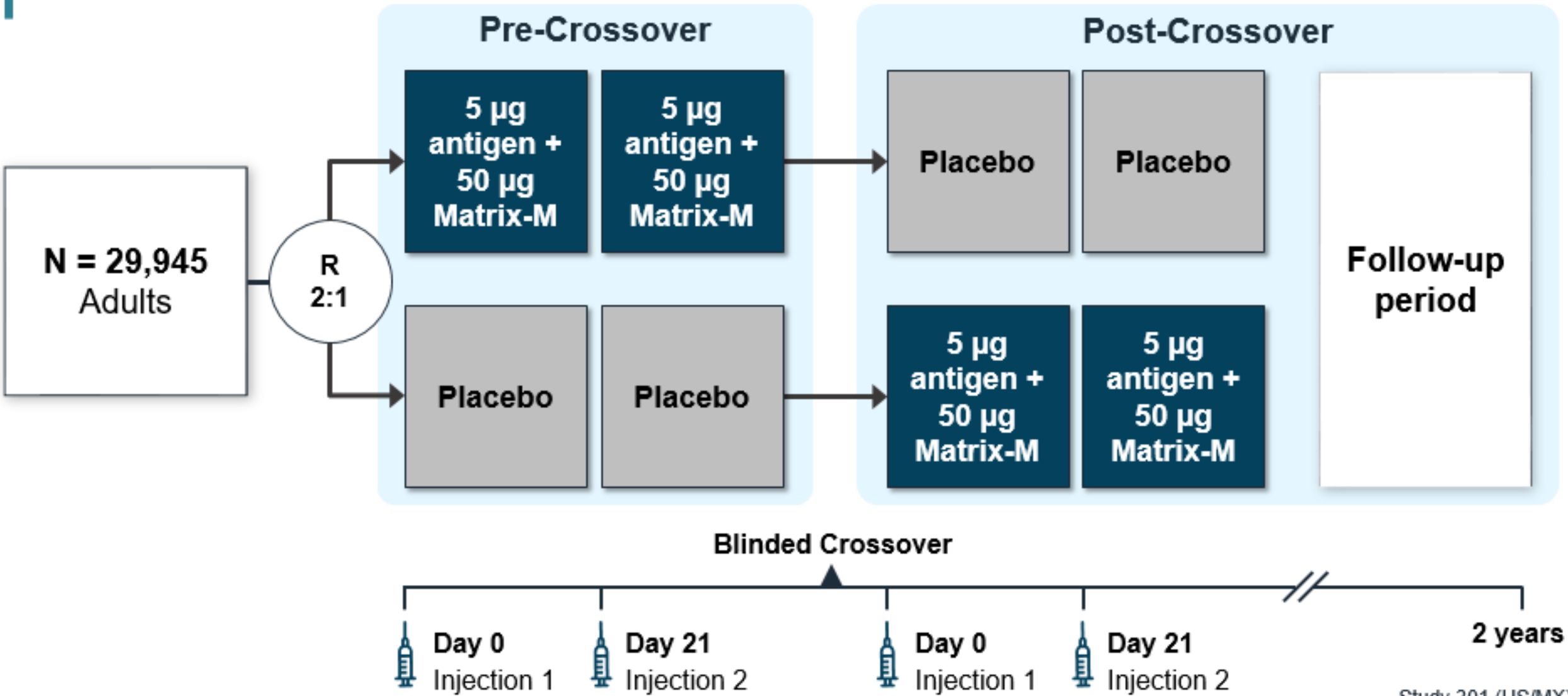
1. Keech et al., NEJM, 2020

Study 301 (US/MX)

PREVENT-19

PRE-fusion protein subunit **V**accine **E**fficacy **N**ovavax **T**rial – COVID-19

Study Design



Study 301 (US/MX)

Efficacy Endpoint Definitions

- **Primary:** first occurrence of PCR-confirmed symptomatic mild, moderate, or severe COVID-19 with onset ≥ 7 days after second dose in serologically negative participants at baseline
  - Primary statistical hypotheses for vaccine efficacy (VE)
    - Lower Bound 95% CI for VE > 30%
- **Secondary:** first occurrence of PCR-confirmed moderate or severe COVID-19, as defined in primary endpoint

Definitions for mild, moderate and severe based on CDC guidance

Variants Represented Most Detected Cases

Variant of Concern/Interest	% of Cases Study 301 (US/MX) (n = 75 cases)
Alpha[1]	53%
Iota[2]	11%
Epsilon[1]	7%
Gamma[1]	4%
Beta[1]	3%
Delta[2]	1%
Kappa[2]	1%
Zeta[2]	1%
Total	81%

1. Variant of Concern; 2. Variant of Interest
CDC: May 25, 2021

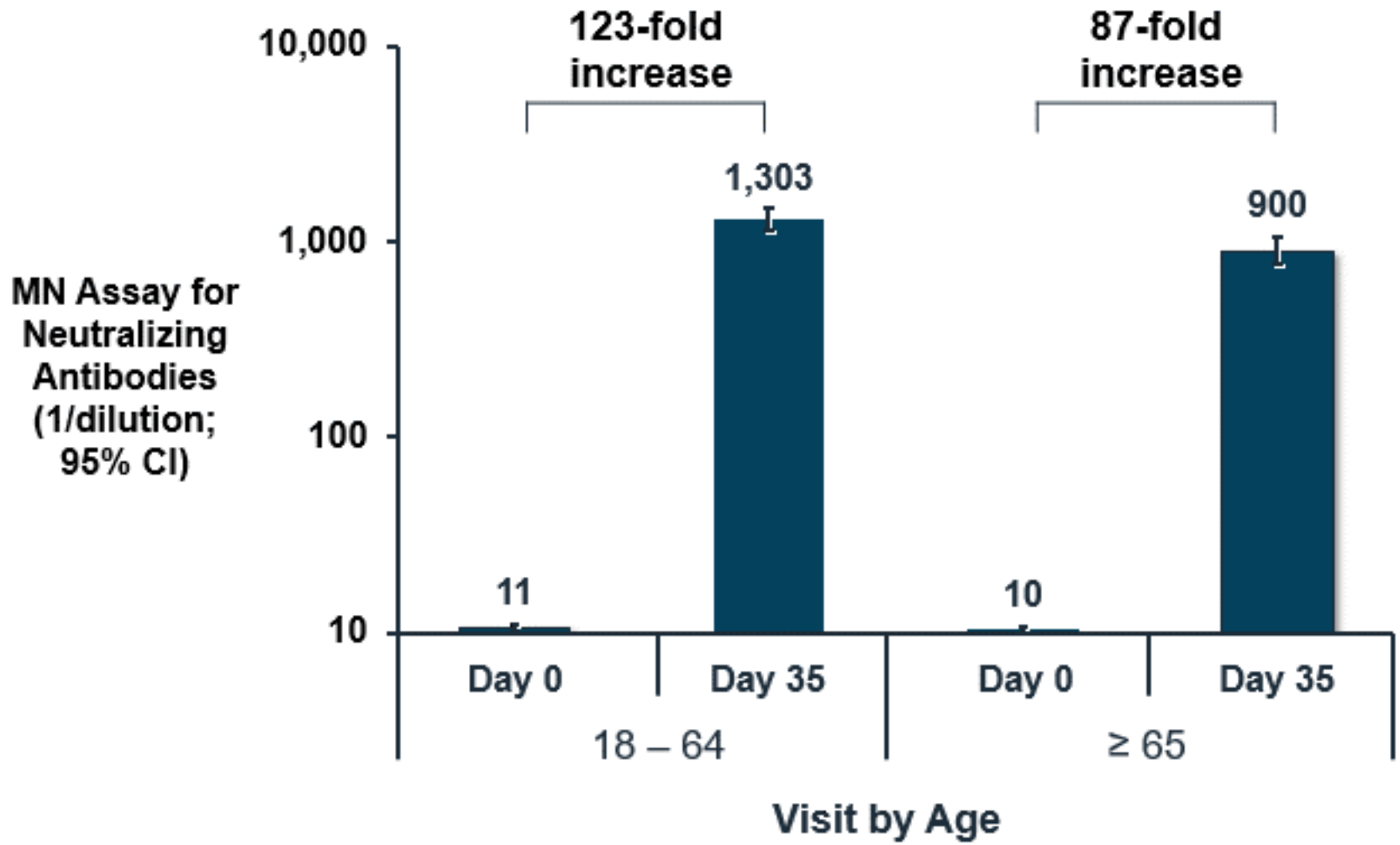
Demographics and Baseline Characteristics Well-Balanced

	NVX-CoV2373 (N = 19,735)	Placebo (N = 9,847)
US | Mexico	**94% | 6%**	**94% | 6%**
Age (years) – median (range)	**47** (18 – 95)	**47** (18 – 90)
≥ 65 years	**13%**	**13%**
Female	**48%**	**49%**
Race		
White	**75%**	**75%**
Black/African American	**12%**	**12%**
American Indian or Alaska Native	**7%**	**7%**
Hispanic/Latino	**22%**	**22%**
BMI ≥ 30 kg/m^2	**37%**	**37%**
High-risk*	**95%**	**95%**
SARS-CoV-2 seropositive	**7%**	**7%**

* Either ≥ 65 years with comorbidities or living or working conditions involving known frequent exposure to COVID-19 or densely populated circumstances

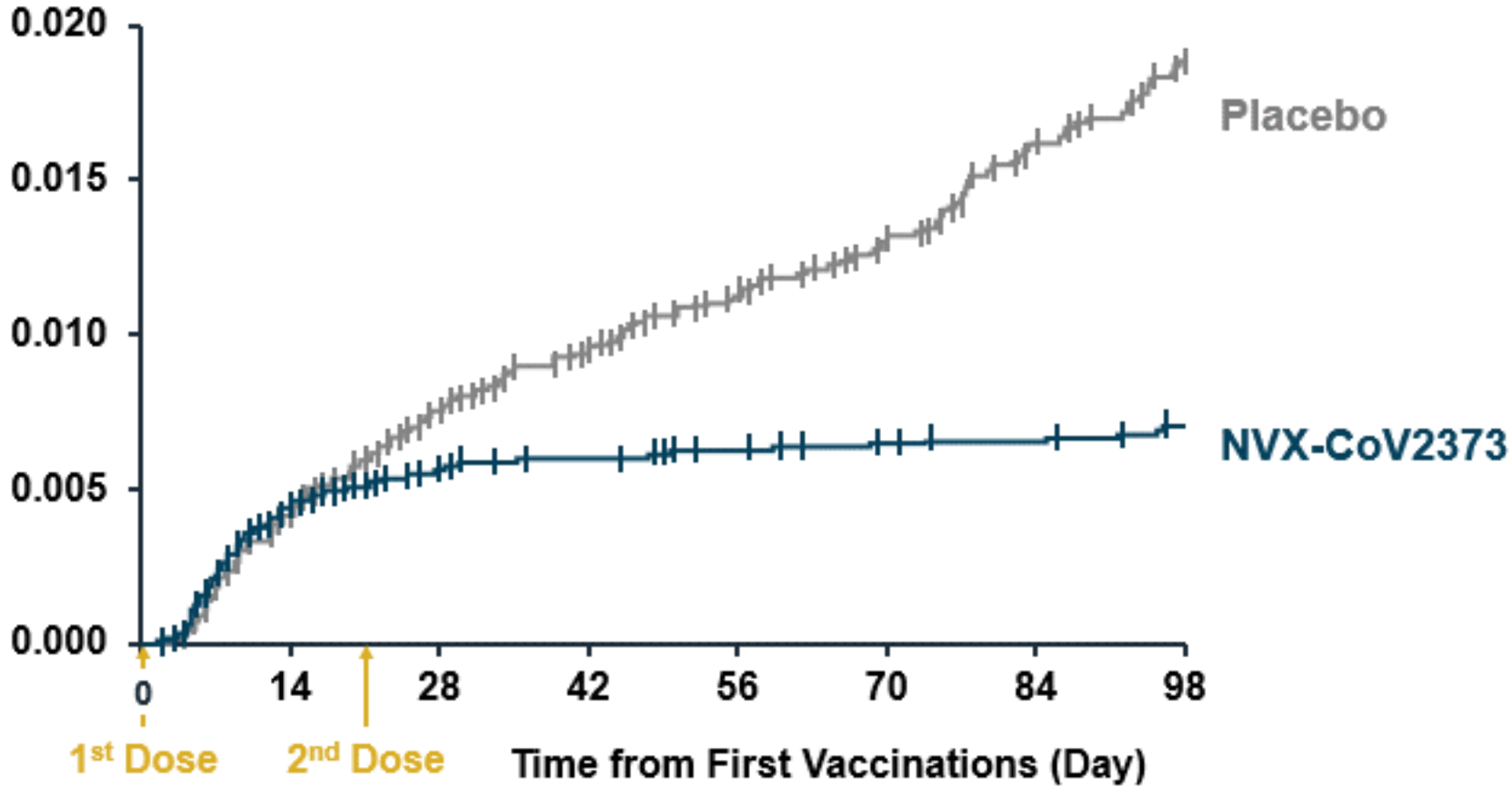
Study 301 (US/MX)

Robust Neutralizing Antibody Responses 14 Days After Second Dose



Study 301 (US/MX)

Efficacy and Durability of Two-Dose Regimen Demonstrated



N at risk

NVX-CoV2373	19,714	19,483	19,000	18,311	17,568	16,863	13,015	7,925
Placebo	9,868	9,720	9,410	8,773	8,082	7,482	5,654	3,445

Updated Efficacy Analysis

Study 301 (US/MX)

NVX-CoV2373 Provides 90% Protection from Mild, Moderate, and Severe COVID-19

100% Protection Against Moderate / Severe Disease

	NVX-CoV2373 (N = 17,272)	**Placebo** (N = 8,385)
Cases	**17 (0.1%)**	**79 (0.9%)**
Mild	*17*	*66*
Moderate	*0*	*9*
Severe	*0*	*4*
Vaccine Efficacy ***Overall***	**90%** (95% CI: 84, 94)	
Vaccine Efficacy ***Moderate/Severe***	**100%** (95% CI: 85, 100)	

NVX-CoV2373 Efficacious Against Original Strain and Variants of Concern/Interest (VoC/VoI)

	PCR-confirmed VoC/VoI		All Other Strains	
	NVX-CoV2373 (N = 17,272)	**Placebo** (N = 8,385)	**NVX-CoV2373** (N = 17,272)	**Placebo** (N = 8,385)
Cases	**8 (< 0.1%)**	**53 (0.6%)**	**1 (< 0.1%)**	**13 (0.2%)**
Mild	*8*	*44*	*1*	*10*
Moderate	*0*	*7*	*0*	*2*
Severe	*0*	*2*	*0*	*1*
Vaccine Efficacy *Overall*	**93%** (95% CI: 86, 97)		**97%** (95% CI: 74, 100)	

Final Efficacy Analysis; Strains for which sequence data are available

Consistent Efficacy Observed Across Subgroups

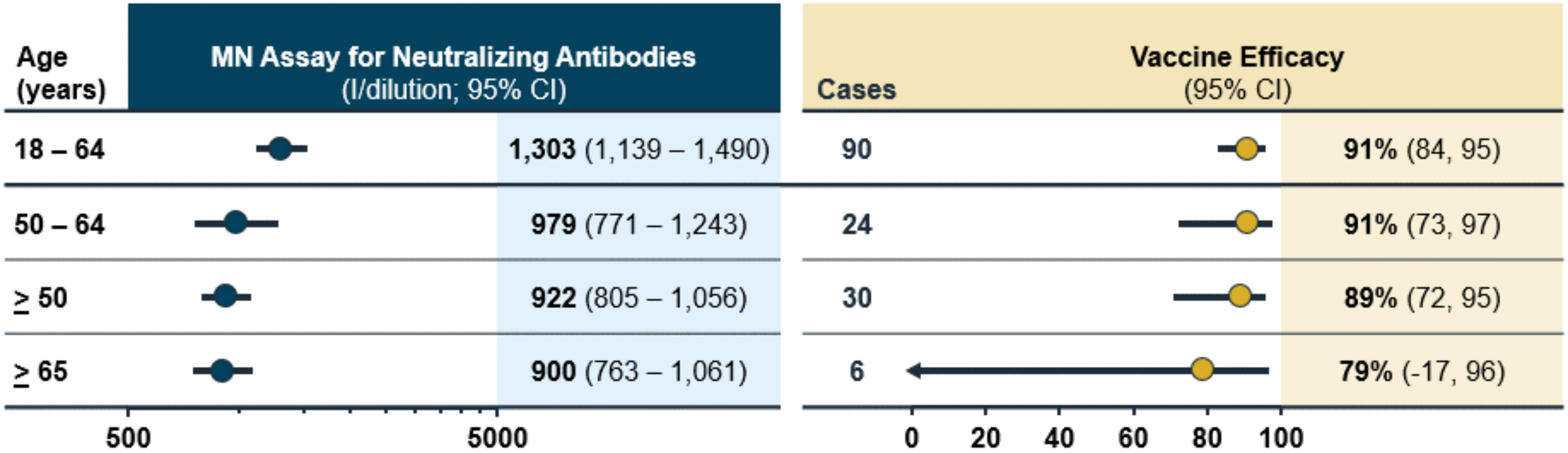
Vaccine Efficacy	Cases: NVX-CoV2373 (N = 17,272)	Cases: Placebo (N = 8,385)	Vaccine Efficacy (95% CI)
Overall	17	79	**90%** (84, 94)
White	13	59	**90%** (82, 95)
Black or African American	1	8	**94%** (51, 99)
American Indian or Alaska Native	1	6	**92%** (33, 99)
Hispanic	9	18	**77%** (49, 90)

Consistent Efficacy Observed Across Subgroups

Vaccine Efficacy	Cases: NVX-CoV2373 (N = 17,272)	Cases: Placebo (N = 8,385)	Vaccine Efficacy (95% CI)
Overall	17	79	**90%** (84, 94)
Severe	0	4	**100%** (33, 100)
Comorbidity, Yes	7	41	**92%** (82, 96)
≥ 65 years	2	4	**79%** (-17, 96)
18 – 64 years	15	75	**91%** (84, 95)

Study 301 (US/MX)

Robust Immunogenicity and Efficacy by Age



Study 301 (US/MX) Efficacy Summary: High Levels of Efficacy in Preventing COVID-19

- Exhibited high level of efficacy for Variants of Concern/Interest
- Provided complete protection from moderate and severe COVID-19
- Demonstrated consistently high efficacy across subgroups

Safety

Denny Kim, MD, MPH

Senior Vice President & Chief Safety Officer
Head of Global Vaccine Safety

Novavax, Inc.

~ 50,000 Participants Across 4 Studies

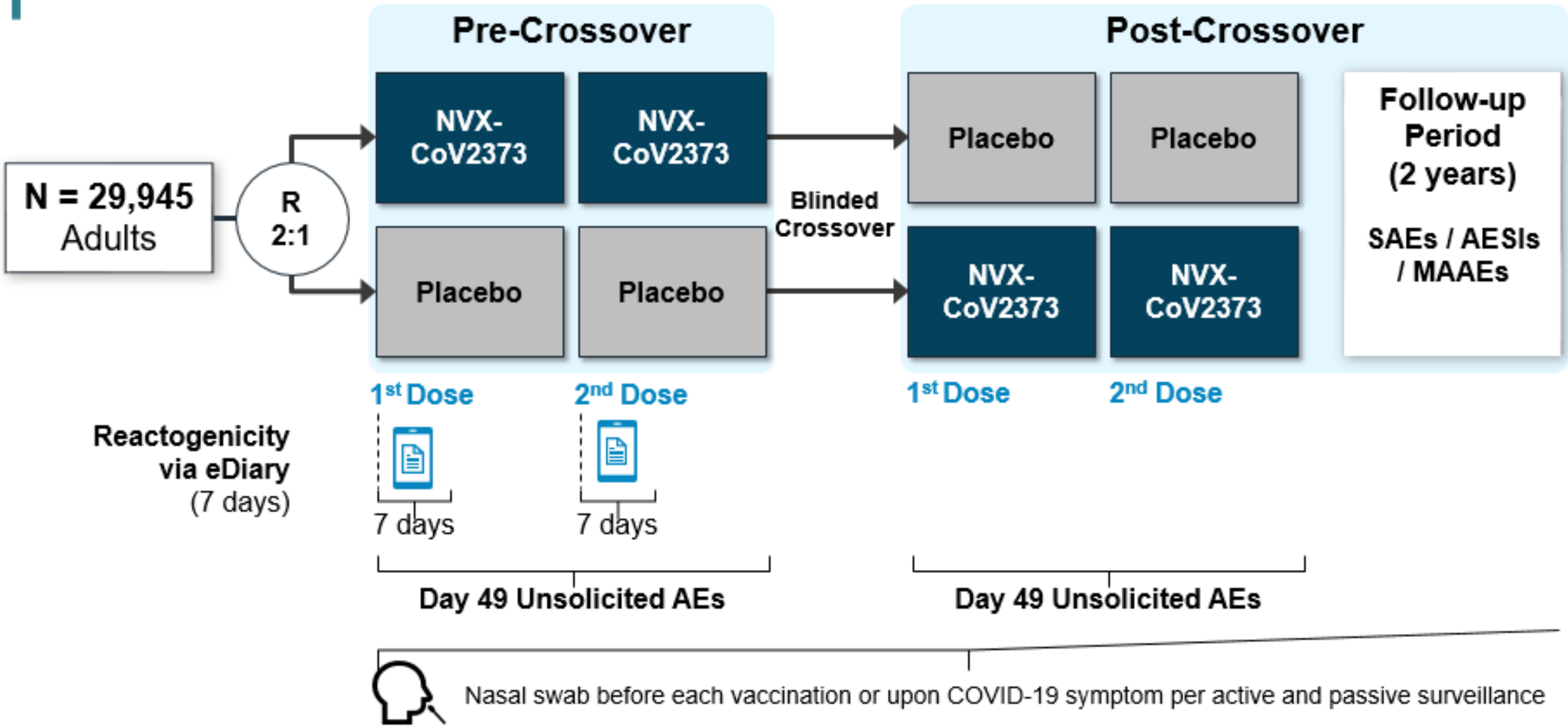
Pooled Safety Data Set

Study (Phase)	**Country**		**NVX-CoV2373**	**Placebo**	**Total**
Total			**30,064**	**19,886**	**49,950**
301 (Phase 3)	US & Mexico	Adult	19,735	9,847	29,582
302 (Phase 3)	UK	Adult	7,575	7,564	15,139
501 (Phase 2a/b)	South Africa	Adult	2,211	2,197	4,408
101 (Phase 1/2)	US & Australia	Adult	543	278	821

Safety Exposure: > 90 Days Median Post-Vaccination Follow-up and High Compliance

	NVX-CoV2373 (N = 19,735)	Placebo (N = 9,847)
Total follow-up, person-years	**5,511**	**2,783**
Median follow-up after 1st vaccination, days	**92**	**89**
Received 2 doses, n (%)	**19,111** (97%)	**9,416** (96%)

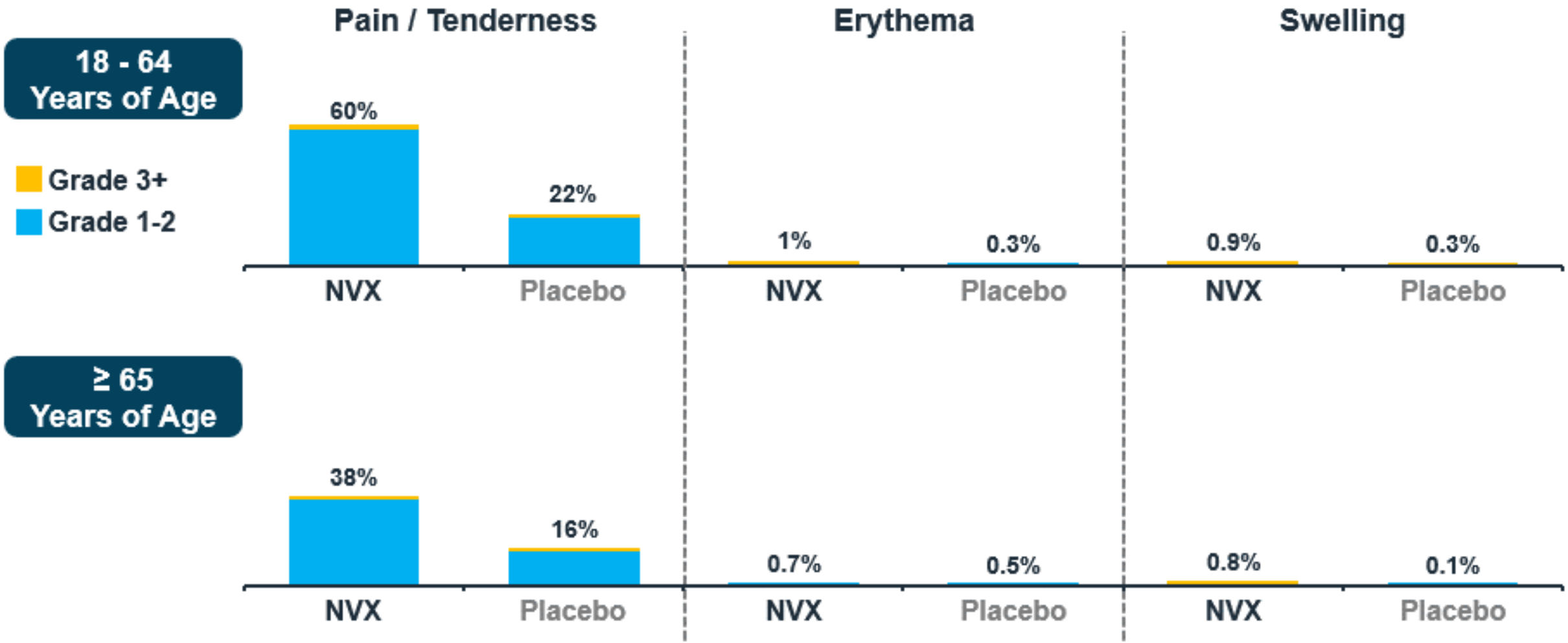
Safety Follow-up



Study 301 (US/MX): Solicited Adverse Events

Collected via e-diary entries for 7 days following each vaccination

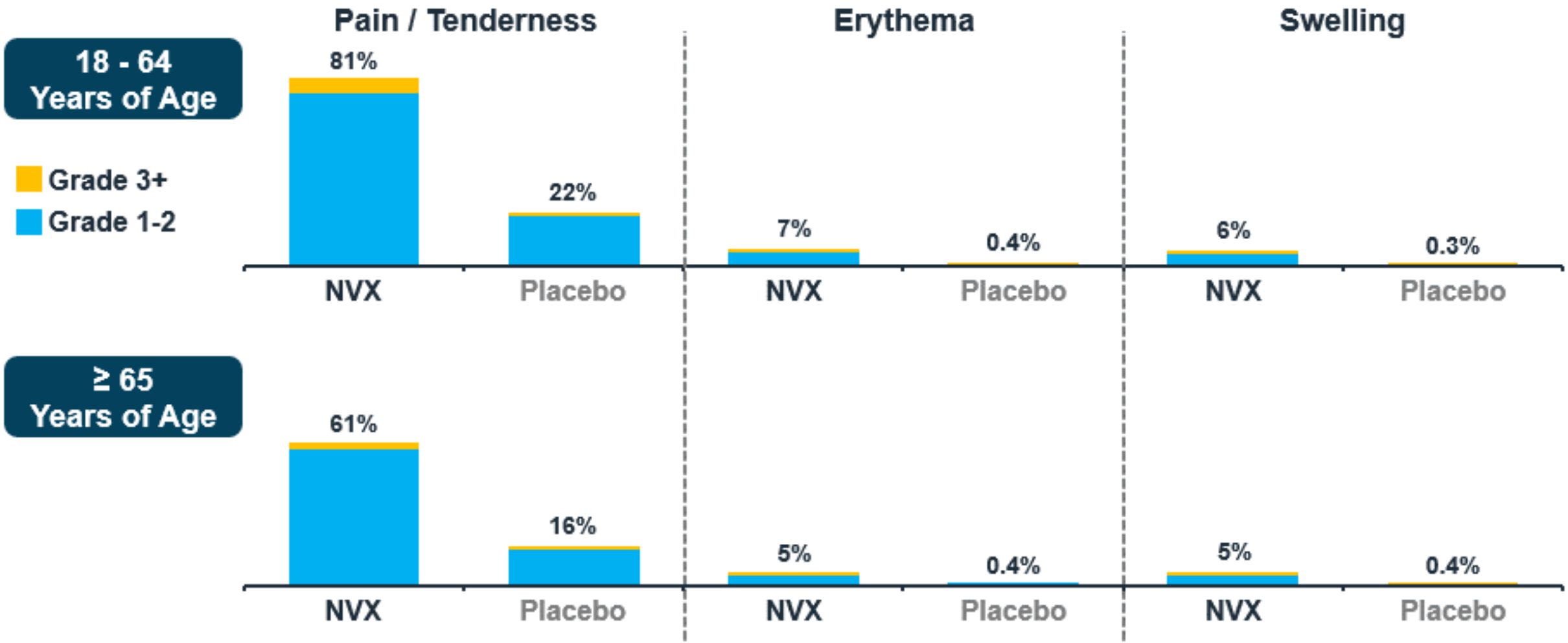
Dose 1 Local Events: Mostly Mild to Moderate, Resolved 1-2 Days



Includes events reported Day 0 to Day 6 post-vaccination; Grades based on FDA guidance

Study 301 (US/MX)

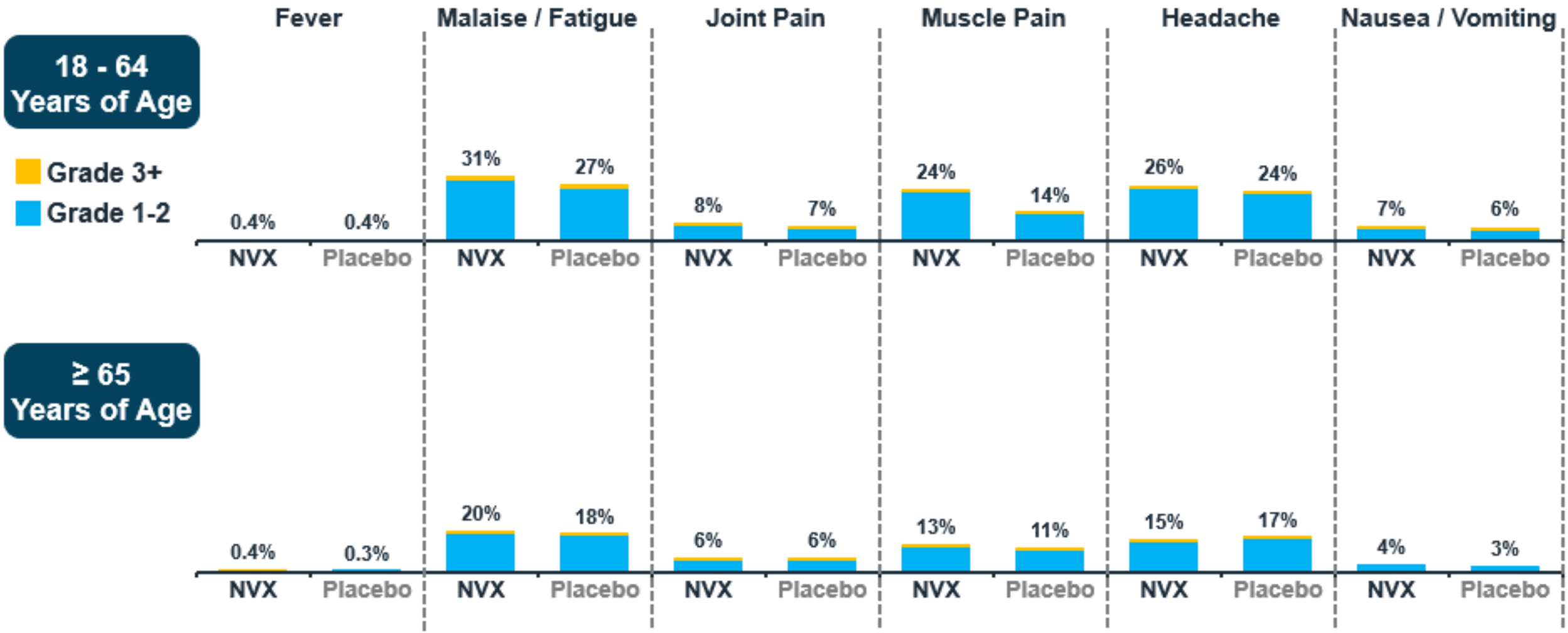
Dose 2 Local Events: Mostly Mild to Moderate, Resolved in 1-2 Days



Includes events reported Day 0 to Day 6 post-vaccination; Grades based on FDA guidance

Study 301 (US/MX)

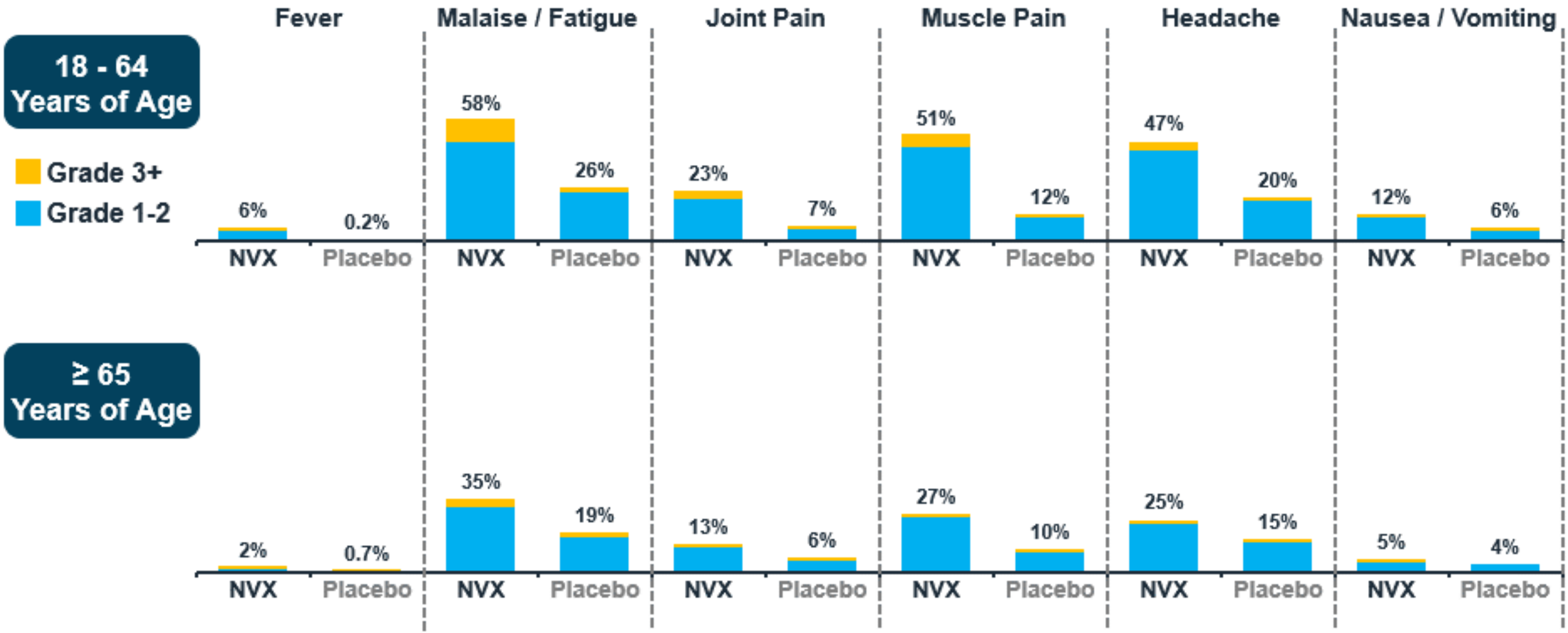
Dose 1 Systemic Events: Most Mild to Moderate, Resolved 1-2 Days



Includes events reported Day 0 to Day 6 post-vaccination; Grades based on FDA guidance

Study 301 (US/MX)

Dose 2 Systemic Events: Most Mild to Moderate, Resolved 1-2 Days



Includes events reported Day 0 to Day 6 post-vaccination; Grades based on FDA guidance

Study 301 (US/MX)

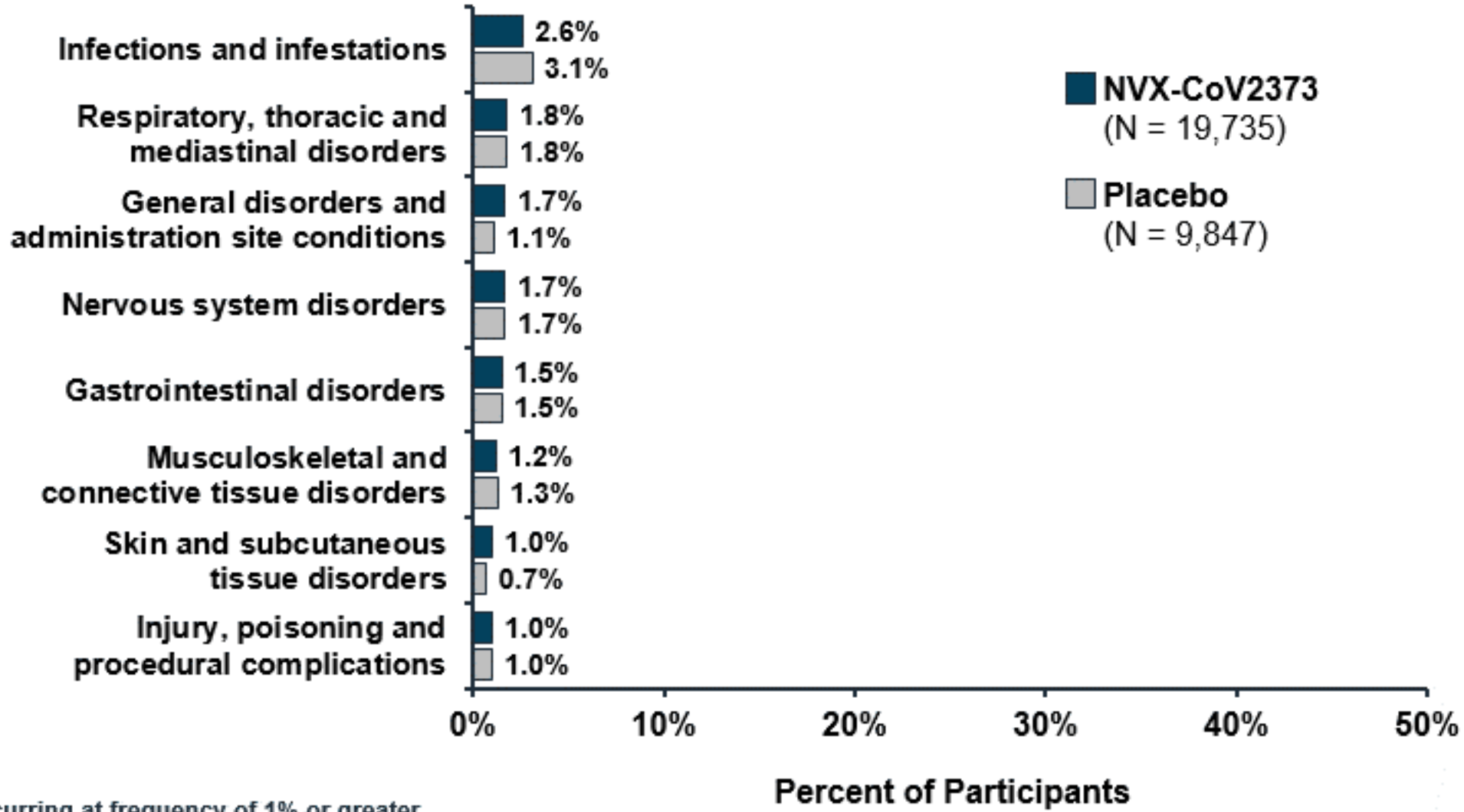
Study 301 (US/MX): Unsolicited Adverse Events

Unsolicited AEs Comparable Between Groups

	Pre-Crossover		Post-Crossover	
	NVX-CoV2373 (N = 19,735)	Placebo (N = 9,847)	NVX-CoV2373 (N = 6,416)	Placebo (N = 15,298)
Any unsolicited AE (non-serious)	11.6%	11.2%	8.1%	5.6%
Severe AE (non-serious)	0.6%	0.4%	0.3%	0.1%
Medically-Attended AE (MAAE)	5.8%	5.7%	4.7%	4.0%
Potential Immune-Mediated Medical Condition (PIMMC)	0.2%	0.2%	0.2%	< 0.1%
Serious AE (SAE)	1.0%	1.1%	1.4%	1.2%
Death	< 0.1%	< 0.1%	< 0.1%	< 0.1%

Rate of AEs Similar and Low in Frequency Through Day 49

Day 0 – Day 49 (28 Days Post Dose 2)



AEs by SOC occurring at frequency of 1% or greater

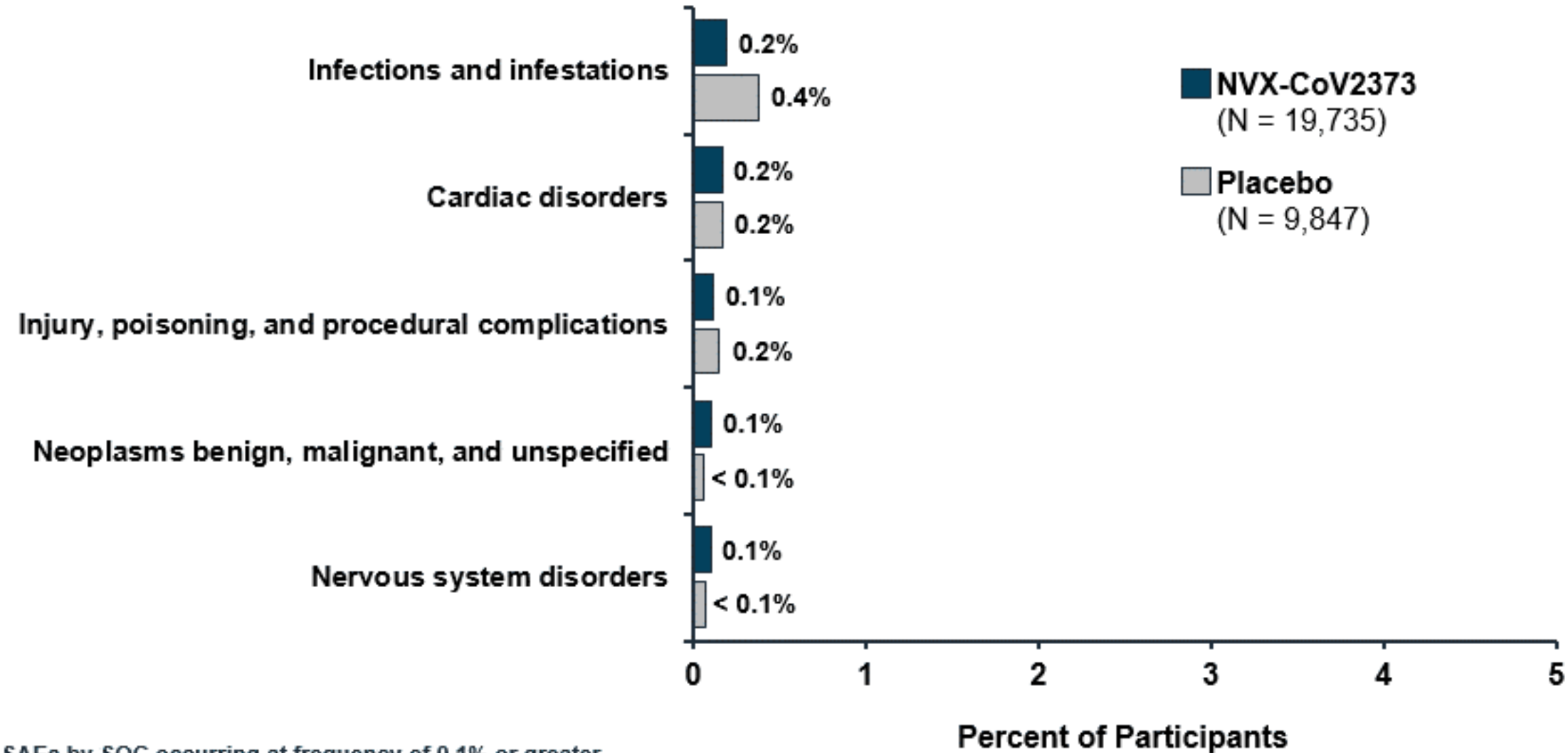
Low Frequency of PIMMC, No Pattern Suggesting Association With Vaccination

Potential Immune-Mediated Medical Condition (PIMMC)	Pre-Crossover				Post-Crossover			
	NVX-CoV2373 (N = 19,735)		Placebo (N = 9,847)		NVX-CoV2373 (N = 6,416)		Placebo (N = 15,298)	
	n	%	n	%	n	%	n	%
Total	35	0.2%	19	0.2%	11	0.2%	15	< 0.1%
Neuropathy peripheral	3	< 0.1%	3	< 0.1%	0	0%	1	< 0.1%
Seizure	3	< 0.1%	2	< 0.1%	1	< 0.1%	1	< 0.1%
Bell's palsy	3	< 0.1%	1	< 0.1%	1	< 0.1%	2	< 0.1%
Uveitis	2	< 0.1%	2	< 0.1%	0	0%	0	0%
Rheumatoid arthritis	2	< 0.1%	1	< 0.1%	2	< 0.1%	1	< 0.1%
Thrombocytopenia	2	< 0.1%	1	< 0.1%	0	0%	2	< 0.1%
Basedow's disease	2	< 0.1%	0	0%	0	0%	0	0%
Ankylosing spondylitis	1	< 0.1%	0	0%	0	0%	2	< 0.1%

Events occurring in > 1 participant, based on investigator reporting and protocol defined criteria

Study 301 (US/MX)

SAEs Occurred Infrequently, Similar Rates Across Treatment Arms



SAEs by SOC occurring at frequency of 0.1% or greater

Study 301 (US/MX)

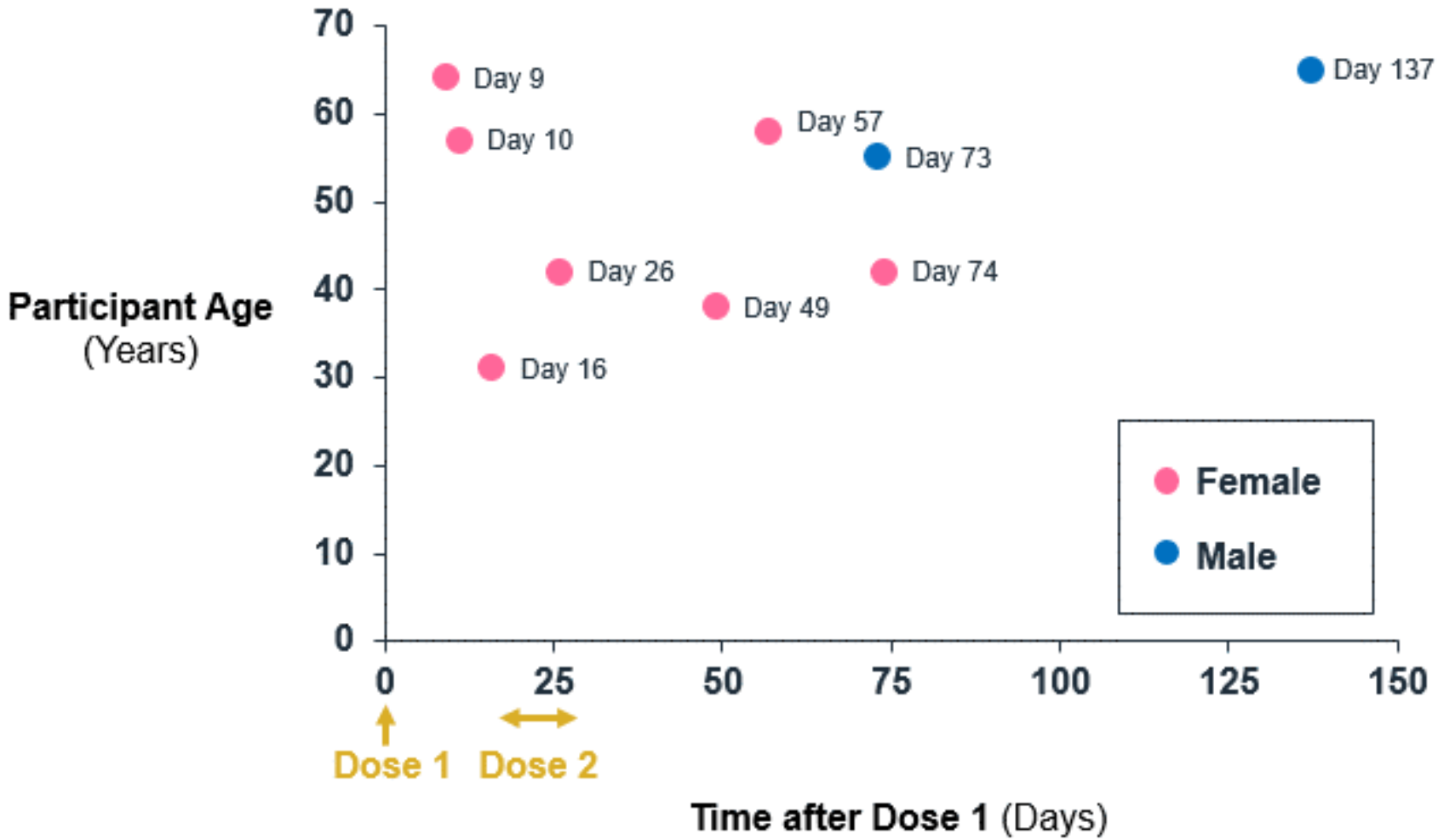
Cholecystitis

Cholecystitis: Weight of Evidence Does Not Suggest Causal Link

- **Cholecystitis / acute cholecystitis events** (*Study 301*)
  - NVX-CoV2373: 9 SAEs (0.05%) 0.16 / 100 PY
  - Placebo: 1 SAE (0.01%) 0.04 / 100 PY
  - Background rate[1] = 0.12 – 0.35 / 100 PY
- 1 case in Study 302; no cases in other Studies 501 and 101
- All events occurred in those with known risk factors for cholecystitis
- All participants had gallstones at time of event onset
- No additional findings from multiple SMQ analyses
- No clustering or temporal relation to treatment
- No post-authorization reports of cholecystitis

1. Expected event rate based on analysis of large administrative claims database (N = 21.4 million patients)

Cholecystitis Time to Onset



Myocarditis/Pericarditis

Myocarditis/Pericarditis Balanced During Placebo-Controlled Phase

- **Placebo-controlled phase: NVX-CoV2373: 0.007% (2 cases); PBO: 0.005% (1 case)**

Study	Treatment	Age	Sex	Time to onset	Dose	Comments
301	Placebo	31	F	72 Days	2nd	Resolved without sequelae
301	NVX-CoV2373	67	M	28 Days	1st	Severe COVID-19
302	NVX-CoV2373	19	M	3 Days	2nd	Resolved without sequelae

Post-Crossover: Myocarditis/Pericarditis Occurred Within Expected Background Rates

- **Post-crossover: Observed 3 cases/14,513 PY; expected background 1.6 – 4.6 cases[1]**

Study	Treatment	Age	Sex	Time to onset	Dose	Comments
301	NVX-CoV2373	16	M	2 Days	2nd	Viral illness, resolved without sequelae
301	NVX-CoV2373	20	M	10 Days	1st	Strep throat (ASO +), lost to follow up
302	NVX-CoV2373	60	F	8 Days	1st	Respiratory tract infection, resolved without sequelae

1. EMA ACCESS
ASO = antistreptolysin-O

Post-Authorization Myocarditis/Pericarditis

- 744,000 doses administered worldwide as of April 30, 2022
- Spontaneous reports from passive surveillance often have limited information
- 35 spontaneous reports of potential myocarditis or pericarditis
  - None met Brighton Collaboration definitive case definition
  - 1 probable myocarditis (47-year-old male, unknown time to onset)
  - 10 probable pericarditis
    - 7 males, 3 females; median age 42 years; 2-14 days time-to-onset from vaccination
    - 1 of 10 probable pericarditis cases with history of mRNA/pericarditis
- All probable cases originate from Australia (17% of total administration)

Data cutoff of April 30, 2022

Ongoing Myocarditis/Pericarditis Surveillance

- Myocarditis/Pericarditis: Important Potential Risk
  - Careful monitoring post-authorization
- Targeted follow-up questionnaires
  - Brighton Collaboration case definition
- Monthly Summary Safety Reports (SSRs) submitted to Health Authorities
- Post-authorization safety studies

Clinical Development: Important Events of Interest

- No cases of anaphylactic reactions
- No cases of Thrombosis with Thrombocytopenia (TTS)
- 1 case of neuropathy meets Brighton Collaboration case definition criteria Guillain-Barré Syndrome (GBS) *(Study 302)*

Pregnancy

Pregnancy was an exclusion criterion

Pregnancy Outcomes for Women Vaccinated with NVX-CoV2373 Across Clinical Program

	Total NVX-CoV2373 (N = 147)	Time of Vaccination in Relation to Last Menstrual Period			
		Before (N = 105)	0-30 days after (N = 22)	> 30 days after (N = 9)	Unknown (N = 11)
Pregnancy outcome	**136**	99	19	8	10
Ongoing	**56**	51	1	3	1
Live birth	**41**	24	12	3	2
Miscarriage	**25**	18	4	1	2
Voluntary termination	**13**	6	2	1	4
Ectopic pregnancy	**1**	0	0	0	1
Stillbirth	**0**	0	0	0	0
Unknown	**11**	6	3	1	1

- Data do not indicate potential risk for mother or fetus

Data as of March 15, 2022

Pooled Safety Data Set

Vaccine Safety Will Be Monitored Following EUA

Plans and strategies to address potential safety concerns

Post-Authorization Pharmacovigilance

- Continue to investigate potential risks
- Supplement routine monitoring
  - Monthly Summary Safety Reports
  - Targeted follow-up questionnaires
  - Qualitative and quantitative reviews for signal detection

VAED = Vaccine-Associated Enhanced Disease

Planned Post-Authorization Studies

Study 401	Study 402	Study 403	Study 404	Study 405
Effectiveness	**Safety**	**Effectiveness**	**Safety**	**Pregnancy**
Against severe COVID-19 in Europe using COVIDRIVE	Using UK Clinical Practice Research Database	Using US Claims and/or Electronic Health Database	Using US Claims and/or Electronic Health Database	COVID-19 Vaccines International Pregnancy Exposure Registry

NVX-CoV2373 Safety Supports Positive Benefit Risk and Favorable Reactogenicity Profile

- **Placebo-Controlled, Pre-Crossover**
  - Well-characterized, exposure in > 30,000 recipients overall
  - Local and systemic events generally Grade 1-2, resolved in 1-2 days
    - Low rates of fever
  - Most AEs mild to moderate severity

- **Long-term follow-up, Post-Crossover (> 40,000 recipients)**
  - SAE rates low, comparable to placebo
  - Continue to monitor for potential risks

Clinical Perspective

Gregory A. Poland, MD, FIDSA, MACP, FRCP
Mary Lowell Leary Emeritus Professor of Medicine
Distinguished Investigator of the Mayo Clinic
Director, Mayo Vaccine Research Group

Our Continuing Challenge

- SARS-CoV-2 challenges and re-challenges us
- Millions of Americans remain unvaccinated
- COVID-19 has long-term, multi-dimensional impacts
- Need for vaccines with different MoAs

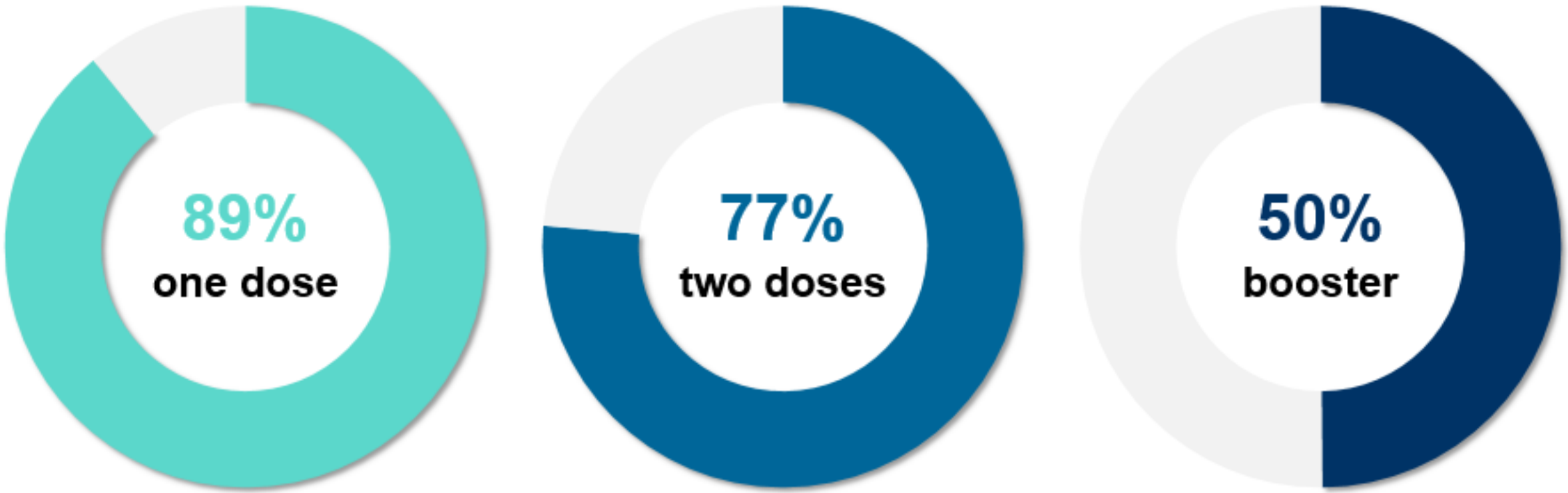
Need Remains for Traditional Vaccine Option

73%

of Americans want COVID-19 vaccines from more traditional method

Ocugen/Harris Poll, February 15, 2022

Percentage of Vaccinated Americans ≥ 18 Years of Age



CDC, May 31, 2022

Benefit of Novavax Vaccine

- Immune-enhancing adjuvant = high efficacy, less reactogenicity
- Most AEs mild-to-moderate, resolved in 1 – 2 days
- Strong efficacy and safety in US/MX against numerous variants[1]
- Similar efficacy and safety seen in published UK study[2,3]

1. Dunkle et al., NEJM, 2021
2. Heath et al., NEJM, 2021
3. Toback et al., The Lancet Res Med, 2021

Signals Broad Cross-Protection

- Robust antibody responses against multiple strains
- Clinical data from Phase 3 trials
- Important to have vaccine platform choices in a constantly evolving pandemic

NVX-CoV2373 Offers Increased Access and Ease of Storage

Immediate Health Impact on Unvaccinated Individuals

4x

greater risk of infection[1]

23x

greater risk of hospitalization[1]

20x

greater risk of dying[1]

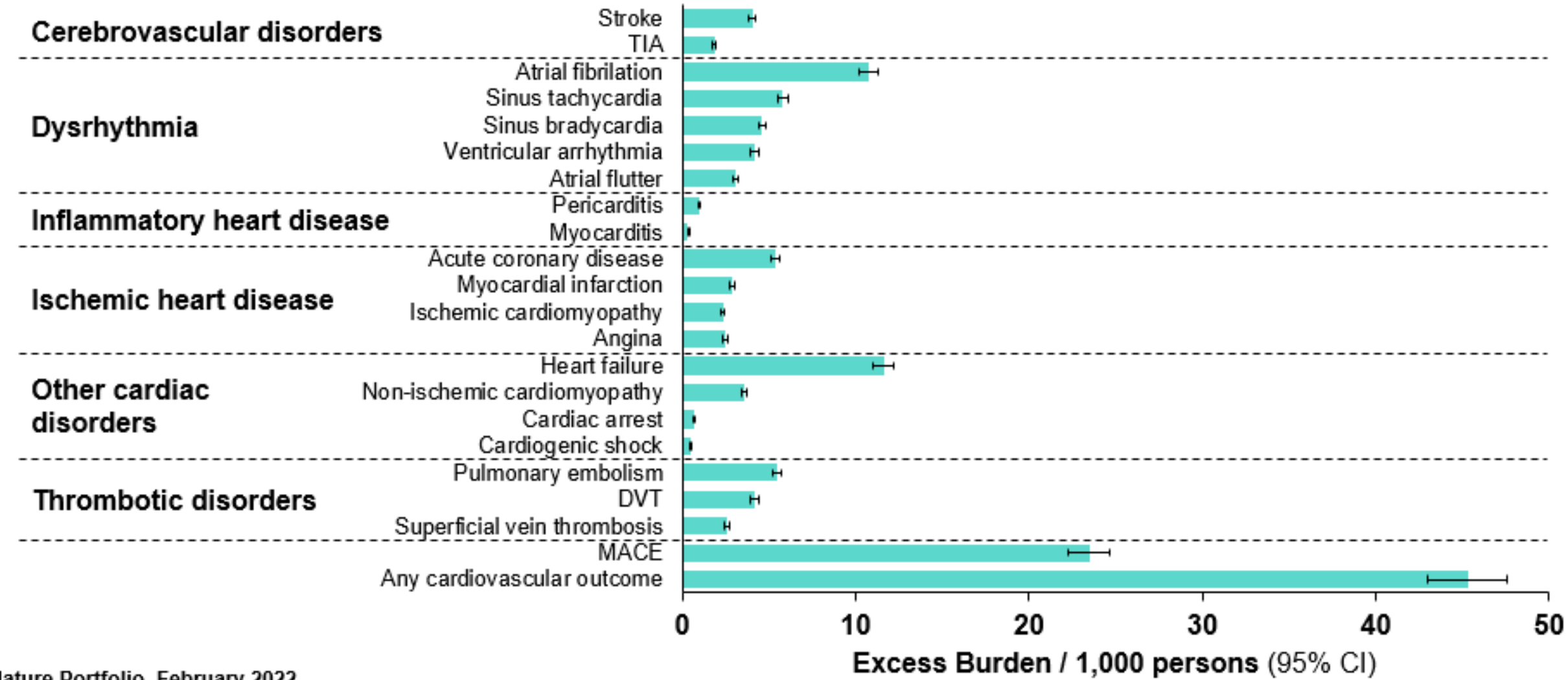
~ 300

people die daily from COVID-19 in US[2]

1. Danza et. al. 2022
2. CDC, May 31, 2022

Long-Term Impact on Individual & Public Health

Higher Risk of 20 Cardiovascular Conditions, With or Without Hospitalization



Nature Portfolio, February 2022

Mental Health Impact Following COVID-19 and Hospitalization

- ~ 60% more likely to experience anxiety and depression
- 46% more likely to have suicidal thoughts
- 34% more likely to develop opioid use disorders

BMJ, February 2022

NVX-CoV2373 Offers Benefits to Stakeholders

Patients / Providers

- Efficacy
- Safety
- Tolerability

Pharmacies / Distributors

- Logistics of distribution, storage, and administration

Employers

- Encourage vaccination

Policymakers

- Ease of access
- Easy to explain to public
- Choice people want

Our Opportunity Today

- Must remain proactive and vigilant in fight against COVID-19
- Authorization important for US and global health
- Goal: Right vaccine, for the right person, for the right purpose, at the right time
- More vaccine options fulfill goal of individualized care

Conclusion

Filip Dubovsky, MD, MPH, FAAP
Executive Vice President & Chief Medical Officer
Novavax, Inc.

Results from NVX-CoV2373 Development Program Support EUA in Adults 18 Years and Older

- Differentiated, well-understood recombinant protein platform
- 90% vaccine efficacy in Phase 3 Study 301 (US/MX)
- Favorable reactogenicity profile and safety data supporting a positive benefit-risk assessment
- Promises to be a useful tool to address the ongoing pandemic

Emergency Use Authorization (EUA) Application for NVX-CoV2373

Novavax, Inc.

Vaccines and Related Biological Products Advisory Committee

June 7, 2022