NAIIS – DEVELOPING COVID-19 VACCINES IN RECORD TIME

November 8, 2021

SETH TOBACK, MD, FAAP

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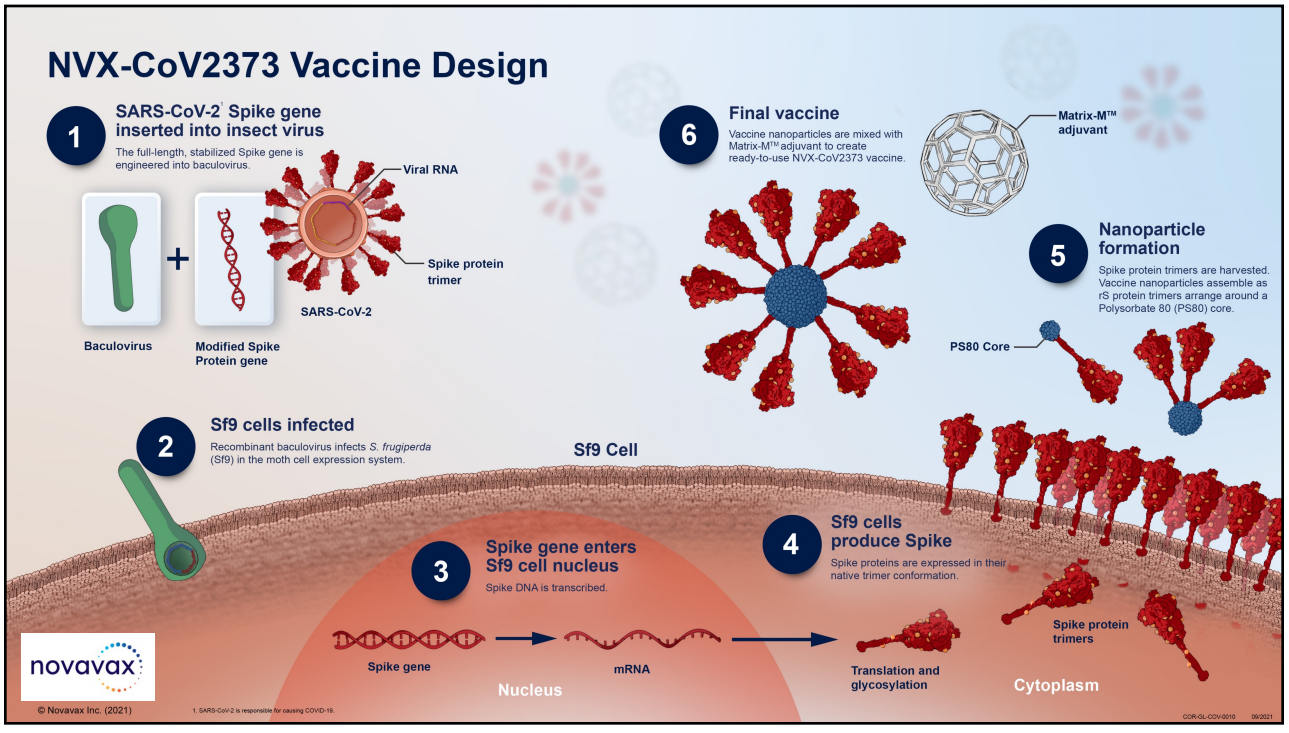

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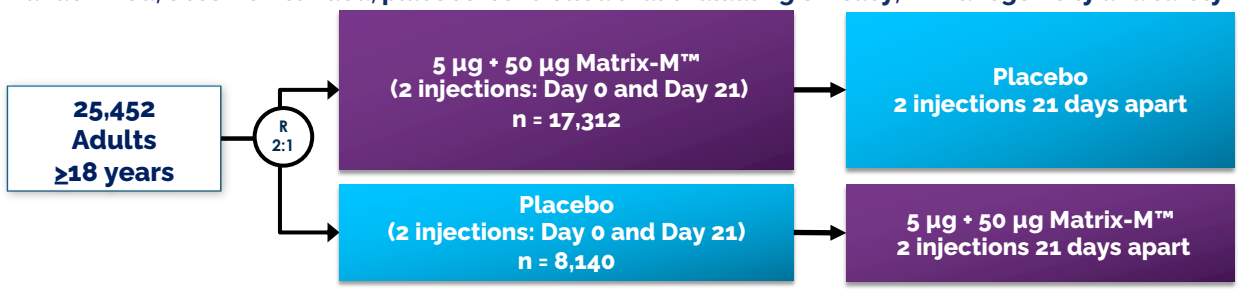
PREVENT-19 Phase 3 Trial

PREVENT-19

Enrollment complete: adult and pediatric cohorts in follow-up
Top-line adult randomized efficacy and safety results available for review

Randomized, observer-blinded, placebo-controlled trial evaluating efficacy, immunogenicity and safety.



- Primary endpoint: PCR-positive symptomatic mild, moderate or severe COVID-19 illness diagnosed ≥ 7 days after second dose

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Dunkle et al., medRxiv Oct 10, 2021.

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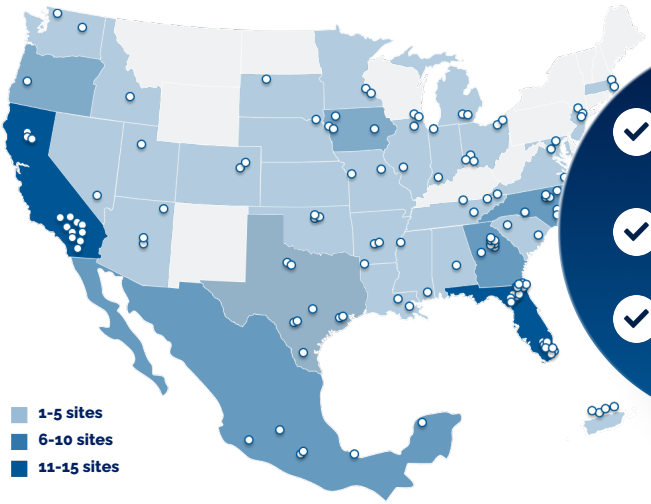
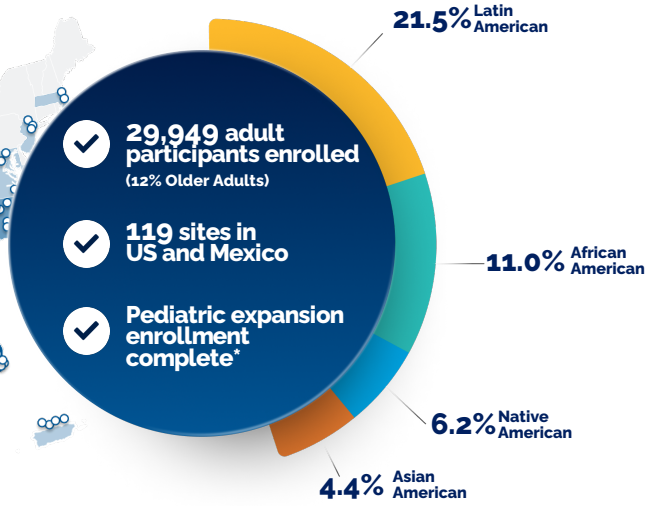
Enrollment and Diversity

PREVENT-19





*Enrollment and diversity data is representative of the main study population (participants ≥18 years) and does not include pediatric expansion participants.

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Dunkle et al., medRxiv Oct 10, 2021.

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High-Level Safety Summary Through Crossover

Serious and Severe adverse events were infrequent and balanced

	NVX-CoV2373 N=19,729	Placebo N=9,853
Any treatment-emergent adverse event	16.3%	14.8%
Any medically attended adverse event	7.0%	6.6%
Any severe treatment-emergent adverse event	1.3%	1.1%
Adverse events of special Interest		
Potentially immune-mediated	0.1%	<0.1%
COVID-19 related	<0.1%	<0.1%
Serious treatment emergent adverse events	0.9%	1.0%
Deaths	0.02%	0%

No single adverse event occurred in more than 1% of vaccine group

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Dunkle et al., medRxiv Oct 10, 2021.

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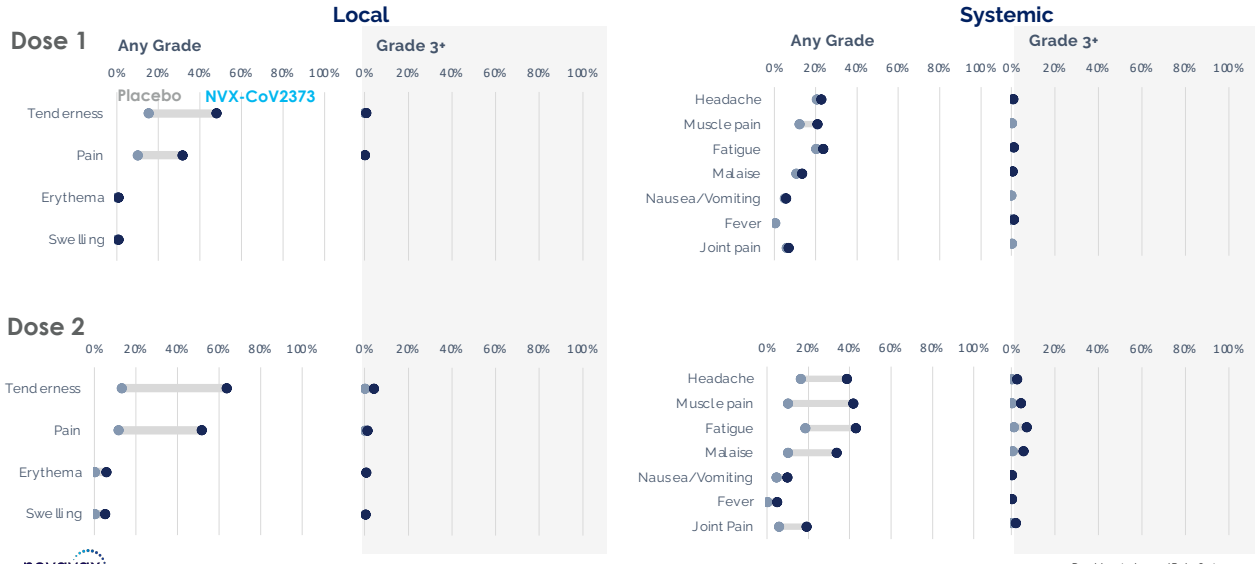
Reactogenicity 7 Days After Dose 1 and Dose 2

Pain and Tenderness most common local symptom ≤ 3 days' duration
Fatigue, Headache, and Muscle Pain most common systemic symptom ≤ 2 days' duration

PREVENT-19



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Dunkle et al., medRxiv Oct 10, 2021.

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Primary Endpoint: PCR-Confirmed Mild, Moderate, or Severe COVID-19 Illness Occurring ≥7 Days After Second Dose in Baseline Seronegative Participants

Primary endpoint: Efficacy against mild, moderate, and severe COVID-19 illness

	NVX-CoV2373 (n=17,298)	Placebo (n=8,077)
Total	**14**	**63**
Mild	*14*	*49*
Moderate	*0*	*10*
Severe	*0*	*4*
Vaccine Efficacy	**90.4%** (95% CI: 82.9; 94.6)	

- Statistical success criteria included lower bound of 95% CI >30%
- 82% of cases caused by Variants of Concern and Variants of Interest
- All breakthrough cases in the vaccine group were mild

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Dunkle et al., medRxiv Oct 10, 2021.

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Key Secondary Endpoint: Efficacy Against Variants NOT Currently Considered Variants of Concern or Variants of Interest

Efficacy for viral isolates NOT currently considered Variants of Concern/Interest

	NVX-CoV2373 (n=17,312)	Placebo (n=8,127)
Total	**0**	**13**
Mild	*0*	*10*
Moderate	*0*	*2*
Severe	*0*	*1*
Vaccine Efficacy	**100%** (95% CI: 85.84; 100)	

- Statistical success criteria included lower bound of 95% CI >30%
- Sequence not available for 23 cases: 21 mild (8 in vaccine, 13 in placebo), 1 moderate in placebo, and 1 severe in placebo

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Dunkle et al., medRxiv Oct 10, 2021.

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Secondary Endpoint: PCR-confirmed Moderate or Severe COVID-19 Illness Occurring ≥7 days After Second Dose in Baseline Seronegative Participants

Efficacy for viral isolates NOT currently considered Variants of Concern/Interest

	NVX-CoV2373 (n=17,312)	Placebo (n=8,126)
Total	**0**	**14**
Moderate	0	10
Severe	0	4
Vaccine Efficacy	**100%** (95% CI: 87.0; 100)	

- Post-hoc analysis for severe disease only VE = 100% (95% CI 34.8; 100)
- An additional 6 COVID-19 hospitalizations (including 1 death) occurred in the placebo group but were not included in the efficacy analysis because PCR samples were not evaluated in the central lab

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Dunkle et al., medRxiv Oct 10, 2021.

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High Levels of Efficacy Maintained Against Variants of Concern and Variants of Interest

Efficacy for viral isolates considered Variants of Concern/Interest[1]

	NVX-CoV2373 (n=17,312)	Placebo (n=8,140)
Total	**7**	**41**
Mild	*7*	*31*
Moderate	*0*	*8*
Severe	*0*	*2*
Vaccine Efficacy	**92.6% (95% CI 83.6; 96.7)**	

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1. Dunkle et al., medRxiv Oct 10, 2021

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Secondary Endpoint: Subgroup Analysis in High-Risk Population

Vaccine efficacy in high-risk population		
	NVX-CoV2373 (n=16,493)	Placebo (n=7,737)
Total	**13**	**62**
Vaccine Efficacy	**91.0%** (95% CI: 83.6; 95.0)	

High Risk Defined as :
- ≥ 65 years of age
- <65 years of age with obesity, chronic kidney disease, chromic lung disease cardiovascular disease, Type 2 diabetes
- Life circumstances with frequent COVID-19 exposure (e.g., meat packing plants) or densely populated living conditions

Dunkle et al., medRxiv Oct 10, 2021.

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NVX-CoV2373 Efficacy Summary

- Results from 2 independent efficacy analyses demonstrate statistically significant efficacy
  - Final UK Phase 3 (N=15,187) VE = 89.7% (95% CI: 80.2; 94.6)[1]
    - Blend of B.1.1.7 variant and non-B.1.1.7 variants
  - Final US Phase 3 (N=25,452) VE = 90.4% (95% CI: 82.9; 94.6)[2]
    - Blend of variants with B.1.1.7 being the most predominant
- Efficacy estimates from post hoc analysis varied with level of drift from prototype sequence used in NVX-CoV2373
  - Alpha — VE = **86.3% to 93.6%**[1,2]
  - Non-VOC/VOI — VE = **96.4% to 100%**[1,2]
  - Beta — VE = **51.0%**[3]
  - Severe disease — VE = **100%**[2]
  - Moderate/Severe disease — VE = **86.9% to 100%**[2,4]
  - Delta — Immunogenicity (next few slides)
- Adolescent data (12-17 years) will be available shortly

1. Heath et al., NEJM 2021. 2. Dunkle et al., medRxiv 2021. 3. Shinde et al., NEJM 2021 4. Novavax, Inc. Data on file.

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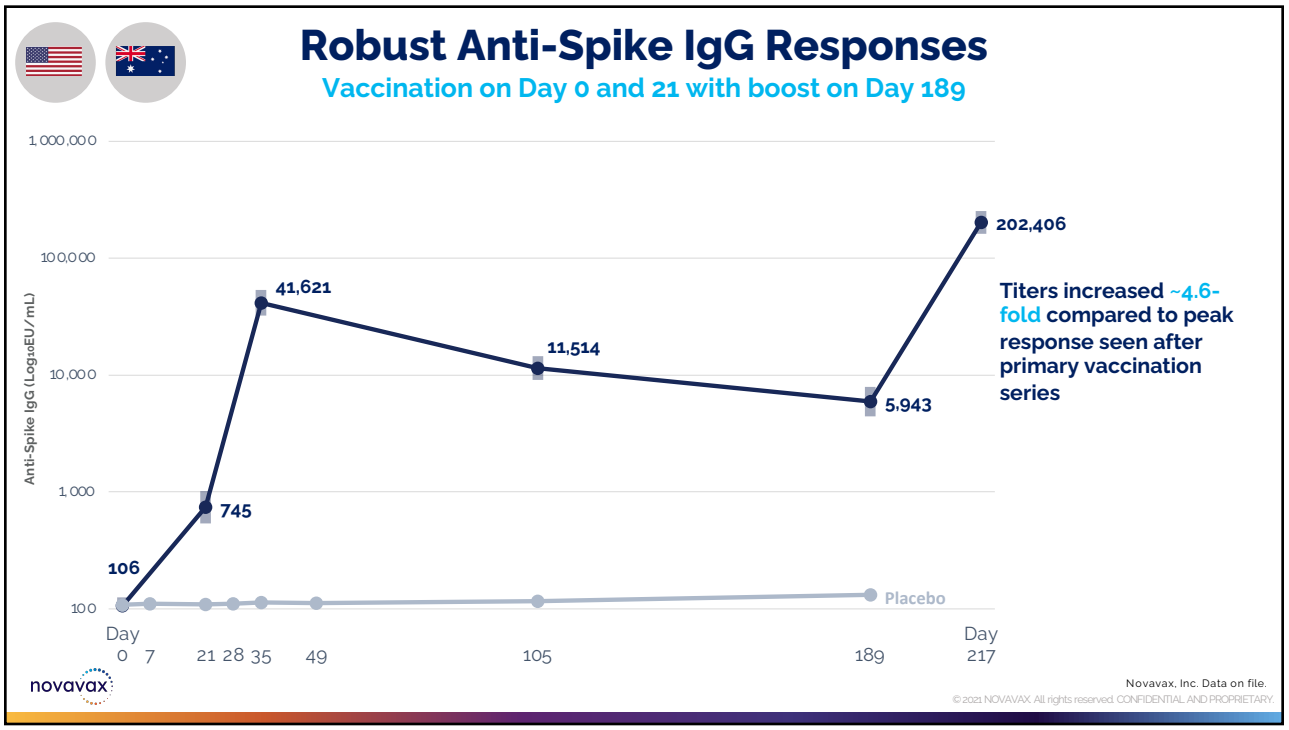
Robust Anti-Spike IgG Responses
Vaccination on Day 0 and 21 with boost on Day 189
1,000,000
100,000
10,000
1,000
100
Anti-Spike IgG (Log10EU/mL)
106
745
41,621
11,514
5,943
202,406
Placebo
Day
0 7 21 28 35 49 105 189
Day
217
Titers increased ~4.6-fold compared to peak response seen after primary vaccination series
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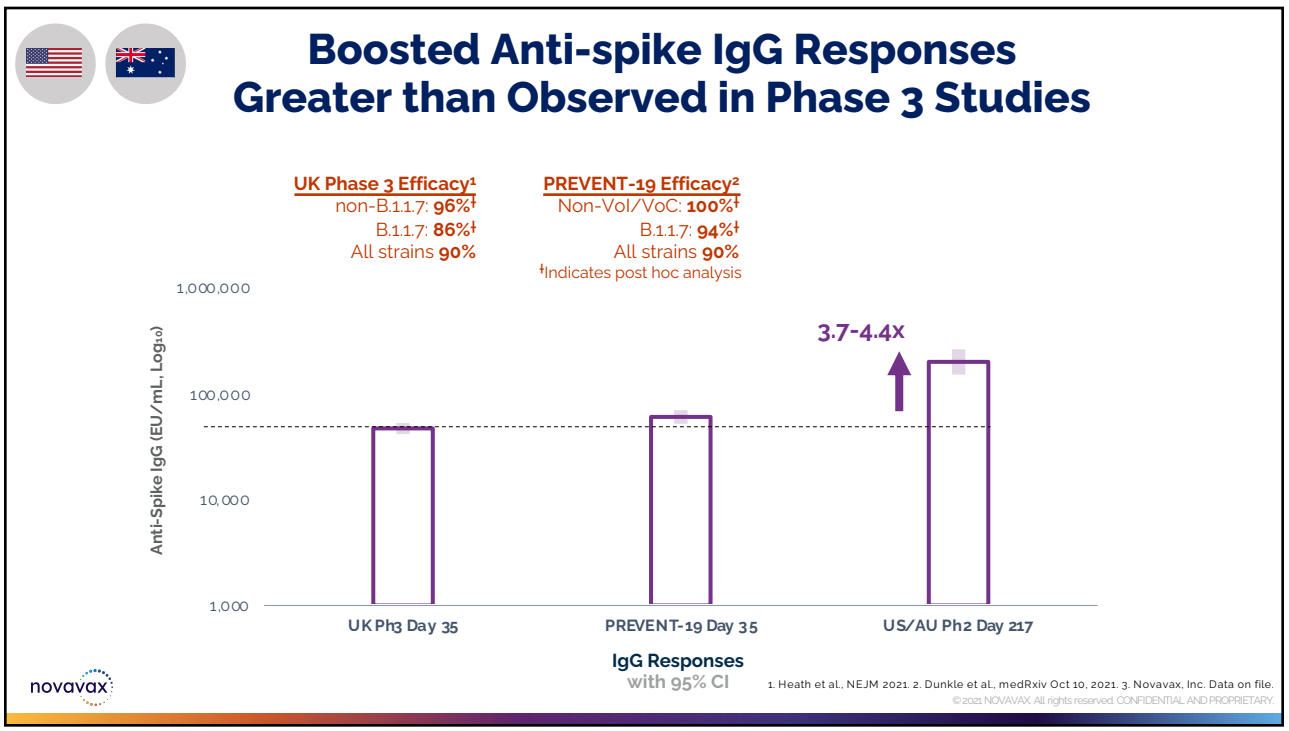
Boosted Anti-spike IgG Responses
Greater than Observed in Phase 3 Studies
UK Phase 3 Efficacy1
non-B.1.1.7: 96%ǂ
B.1.1.7: 86%ǂ
All strains 90%
PREVENT-19 Efficacy2
Non-VoI/VoC: 100%ǂ
B.1.1.7: 94%ǂ
All strains 90%
ǂIndicates post hoc analysis
1,000,000
100,000
10,000
1,000
Anti-Spike IgG (EU/mL, Log10)
3.7-4.4x
UK Ph3 Day 35
PREVENT-19 Day 35
US/AU Ph2 Day 217
IgG Responses
with 95% CI
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1. Heath et al., NEJM 2021. 2. Dunkle et al., medRxiv Oct 10, 2021. 3. Novavax, Inc. Data on file.
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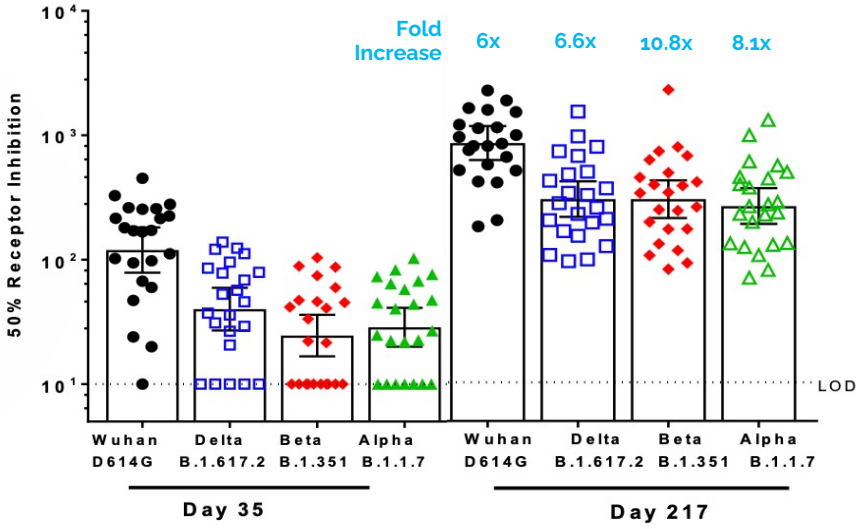
Functional hACE2 Inhibition Responses Increased for All Variants with a Single Booster Dose of NVX-CoV2373

Post-boost consistency suggests maturation of immune response



Novavax, Inc. Data on file.

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NVX-CoV2373 Investigational Vaccine Candidate Administration and Storage

- Two 0.5 mL doses 3 to 4 weeks apart via intramuscular injection.
- Administer using 1-mL syringe and standard 22- to 25-gauge needle.
- No reconstitution or dilution required.
- Each multi-dose vial contains 10 doses (0.5 mL/dose).
- Store in refrigerator at 2°C to 8°C (36°F to 46°F); do not freeze.
- Does not contain preservative; store opened vial between 2°C to 25°C for up to 6 hours after first puncture.
- Proposed use: 18 years old and up, primary 2-dose series
- Timeline: 110 million doses, US regulatory submission-rolling

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