

Supplementary Material

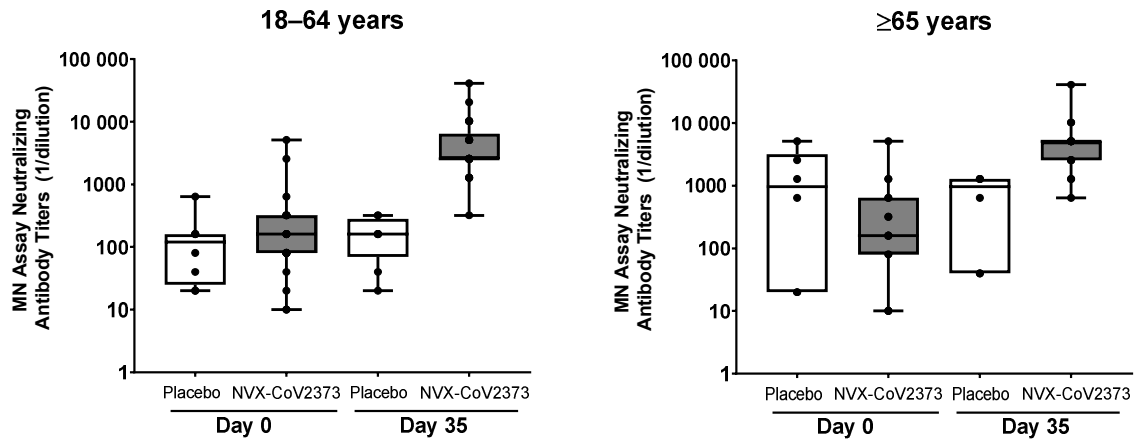


Figure S1. SARS-CoV-2 neutralizing antibody responses in participants who were seropositive/RT-PCR-positive at baseline (PP-IMM-2 Analysis Set). Panel A: participants 18 to 64 years, Panel B: participants ≥ 65 years. Abbreviations: MN, microneutralization; PP-IMM, Per-Protocol Immunogenicity analysis set; RT-PCR, reverse transcriptase polymerase chain reaction; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

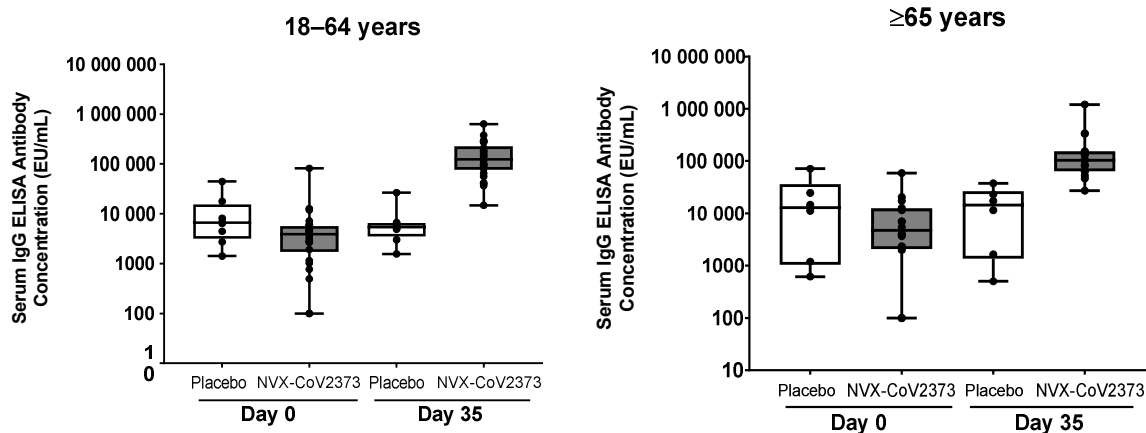


Figure S2. SARS-CoV-2 anti-spike IgG antibody responses in participants who were seropositive/RT-PCR-positive at baseline (PP-IMM-2 Analysis Set). Panel A: participants 18 to 64 years, Panel B: participants ≥ 65 years. Abbreviations: ELISA, enzyme-linked immunosorbent assay; EU/mL, ELISA units per mL; IgG, immunoglobulin; RT-PCR, reverse transcriptase polymerase chain reaction; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

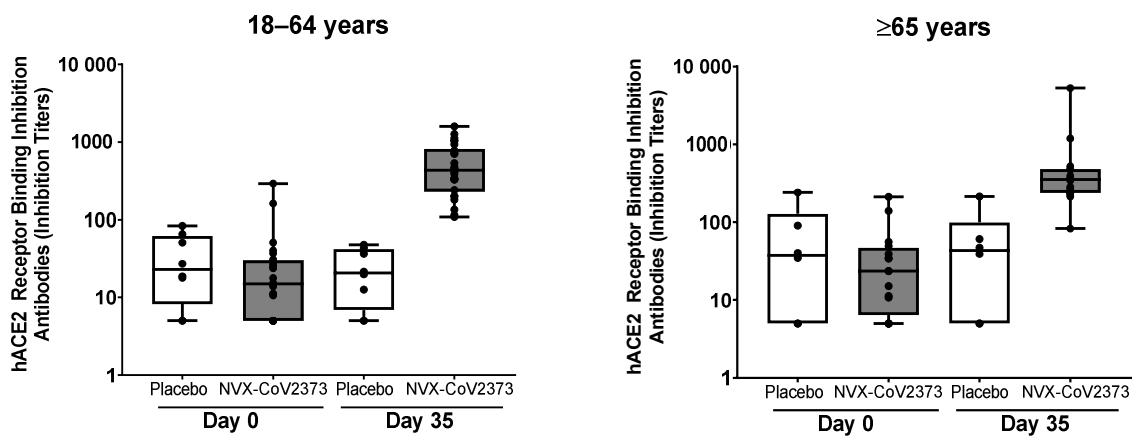


Figure S3. hACE2 receptor inhibition antibody responses in participants who were seropositive/RT-PCR-positive at baseline (PP-IMM-2 Analysis Set). Panel A: participants 18 to 64 years, Panel B: participants ≥ 65 years. Abbreviations: hACE2, human angiotensin converting enzyme 2; RT-PCR, reverse transcriptase polymerase chain reaction.

Table S1. Demographic Characteristics (Per-Protocol Immunogenicity Analysis Set, 18 to 64 Years)

Parameter, n (%)	NVX-CoV2373 N = 359	Placebo N = 171	Total N = 530
Sex			
Male	185 (51.5)	80 (46.8)	265 (50.0)
Female	174 (48.5)	91 (53.2)	265 (50.0)
Age (years)			
Mean (SD)	44.6 (12.33)	42.7 (12.79)	43.9 (12.50)
Median	46.0	43.0	45.0
Min–max	18–64	18–64	18–64
Race			
White	289 (80.5)	129 (75.4)	418 (78.9)
Black or African American	31 (8.6)	22 (12.9)	53 (10.0)
American Indian or Alaska Native	17 (4.7)	5 (2.9)	22 (4.2)
Native Hawaiian or Other Pacific Islander	—	1 (0.6)	1 (0.2)
Asian	13 (3.6)	13 (7.6)	26 (4.9)
Mixed Origin	7 (1.9)	1 (0.6)	8 (1.5)
Not Reported	2 (0.6)	—	2 (0.4)
Ethnicity			
Hispanic or Latino	82 (22.8)	34 (19.9)	116 (21.9)

Parameter, n (%)	NVX-CoV2373	Placebo	Total
	N = 359	N = 171	N = 530
Not Hispanic or Latino	276 (76.9)	137 (80.1)	413 (77.9)
Not Reported	1 (0.3)	—	1 (0.2)
Country			
Mexico	18 (5.0)	8 (4.7)	26 (4.9)
United States	341 (95.0)	163 (95.3)	504 (95.1)

Abbreviations: SD, standard deviation.

Table S2. Demographic Characteristics (Per-Protocol Immunogenicity Analysis Set, ≥65 Years)

Parameter, n (%)	NVX-CoV2373 N = 358	Placebo N = 175	Total N = 533
Sex			
Male	181 (50.6)	85 (48.6)	266 (49.9)
Female	177 (49.4)	90 (51.4)	267 (50.1)
Age (years)			
Mean (SD)	69.8 (4.93)	70.3 (4.20)	69.9 (4.70)
Median	68.0	69.0	69.0
Min–max	65–95	65–87	65–95
Race			
White	284 (79.3)	136 (77.7)	420 (78.8)
Black or African American	31 (8.7)	25 (14.3)	56 (10.5)
American Indian or Alaska Native	32 (8.9)	11 (6.3)	43 (8.1)
Native Hawaiian or Other Pacific Islander	—	—	—
Asian	7 (2.0)	1 (0.6)	8 (1.5)
Mixed Origin	3 (0.8)	1 (0.6)	4 (0.8)
Not Reported	1 (0.3)	1 (0.6)	2 (0.4)
Ethnicity			
Hispanic or Latino	61 (17.0)	27 (15.4)	88 (16.5)

Parameter, n (%)	NVX-CoV2373	Placebo	Total
	N = 358	N = 175	N = 533
Not Hispanic or Latino	297 (83.0)	148 (84.6)	445 (83.5)
Not Reported	1 (0.3)	1 (0.6)	2 (0.4)
Country			
Mexico	32 (8.9)	15 (8.6)	47 (8.8)
United States	326 (91.1)	160 (91.4)	486 (91.2)

Abbreviations: SD, standard deviation.

Table S3. Demographic Characteristics (Per-Protocol Immunogenicity Analysis Set 2, 18 to 64 Years)

Parameter, n (%)	NVX-CoV2373 N = 385	Placebo N = 179	Total N = 564
Sex			
Male	197 (51.2)	83 (46.4)	280 (49.6)
Female	188 (48.8)	96 (53.6)	284 (50.4)
Age (years)			
Mean (SD)	44.6 (12.39)	42.5 (12.83)	43.9 (12.56)
Median	46.0	43.0	45.0
Min–max	18–64	18–64	18–64
Race			
White	303 (78.7)	132 (73.7)	435 (77.1)
Black or African American	41 (10.6)	24 (13.4)	65 (11.5)
American Indian or Alaska Native	19 (4.9)	7 (3.9)	26 (4.6)
Native Hawaiian or Other Pacific Islander	—	1 (0.6)	1 (0.2)
Asian	13 (3.4)	14 (7.8)	27 (4.8)
Mixed Origin	7 (1.8)	1 (0.6)	8 (1.4)
Not Reported	2 (0.5)	—	2 (0.4)
Ethnicity			
Hispanic or Latino	96 (24.9)	36 (20.1)	132 (23.4)

Parameter, n (%)	NVX-CoV2373	Placebo	Total
	N = 385	N = 179	N = 564
Not Hispanic or Latino	288 (74.8)	143 (79.9)	431 (76.4)
Not Reported	1 (0.3)	—	1 (0.2)
Country			
Mexico	22 (5.7)	10 (5.6)	32 (5.7)
United States	363 (94.3)	169 (94.4)	532 (94.3)

Abbreviations: SD, standard deviation.

Table S4. Demographic Characteristics (Per-Protocol Immunogenicity Analysis Set 2, ≥65 Years)

Parameter, n (%)	NVX-CoV2373 N = 374	Placebo N = 181	Total N = 555
Sex			
Male	189 (50.5)	88 (48.6)	277 (49.9)
Female	185 (49.5)	93 (51.4)	278 (50.1)
Age (years)			
Mean (SD)	69.7 (4.85)	70.2 (4.18)	69.9 (4.65)
Median	68.0	69.0	69.0
Min–max	65–95	65–87	65–95
Race			
White	294 (78.6)	139 (76.8)	433 (78.0)
Black or African American	35 (9.4)	26 (14.4)	61 (11.0)
American Indian or Alaska Native	34 (9.1)	13 (7.2)	47 (8.5)
Native Hawaiian or Other Pacific Islander	—	—	—
Asian	7 (1.9)	1 (0.6)	8 (1.4)
Mixed Origin	3 (0.8)	1 (0.6)	4 (0.7)
Not Reported	1 (0.3)	1 (0.6)	2 (0.4)
Ethnicity			
Hispanic or Latino	64 (17.1)	30 (16.6)	94 (16.9)

Parameter, n (%)	NVX-CoV2373	Placebo	Total
	N = 374	N = 181	N = 555
Not Hispanic or Latino	310 (82.9)	151 (83.4)	461 (83.1)
Not Reported	—	—	—
Country			
Mexico	35 (9.4)	17 (9.4)	52 (9.4)
United States	339 (90.6)	164 (90.6)	503 (90.6)

Abbreviations: SD, standard deviation.

Table S5. Neutralizing Antibodies for SARS-CoV-2 Wild-Type Virus at Day 0 (Baseline) and Day 35 (14 Days After Second Vaccination) in Adult Participants by Baseline Serostatus (PP-IMM-2 Analysis Set)

Parameter	Serologically/RT-PCR Negative		Serologically/RT-PCR Positive	
	NVX-CoV2373 N = 717	Placebo N = 346	NVX-CoV2373 N = 42	Placebo N = 14
Day 0 (baseline)				
n1	714	344	41	14
GMT	10.5	10.1	160.0	168.1
95% CI ^a	10.2, 10.9	10.0, 10.1	97.4, 262.9	55.7, 507.1
Day 35				
n1	709	345	42	14
GMT	1082.9	10.8	3741.9	195.0
95% CI ^a	973.0, 1205.3	10.2, 11.3	2754.9, 5082.5	87.0, 437.1

Abbreviations: CI, confidence interval; GMT, geometric mean titer; n1, number of participants in the PP-IMM-2 Analysis Set with non-missing data at visit; PP-IMM-2, Per Protocol Immunogenicity 2; RT-PCR, reverse transcriptase polymerase chain reaction.

^aThe 95% CI for GMT were calculated based on the t-distribution of the log-transformed values, then back transformed to the original scale for presentation.

Table S6. Serum IgG Antibody Concentrations to SARS-CoV-2 S Protein at Day 0 (Baseline) and Day 35 (14 Days After Second Vaccination) in Adult Participants by Baseline Serostatus (PP-IMM-2 Analysis Set)

Parameter	Serologically/RT-PCR Negative		Serologically/RT-PCR Positive	
	NVX-CoV2373	Placebo	NVX-CoV2373	Placebo
	N = 717	N = 346	N = 42	N = 14
Day 0 (baseline)				
n1	717	345	42	14
GMEU	119.2	108.2	3062.2	7212.4
95% CI ^a	112.8, 125.9	104.5, 112.1	1859.6, 5042.6	3253.5, 15 988.5
Day 35				
n1	717	344	42	14
GMEU	49 270.7	126.7	119 620.4	6135.6
95% CI ^a	44 521.3, 54 526.8	115.6, 139.0	91 715.7, 156 015.1	3042.4, 12 373.9

Abbreviations: CI, confidence interval; ELISA, enzyme-linked immunosorbent assay; GMEU, geometric mean ELISA units; IgG, immunoglobulin G; n1, number of participants in the PP-IMM-2 Analysis Set with non-missing data at visit; PP-IMM-2, Per Protocol Immunogenicity 2; RT-PCR, reverse transcriptase polymerase chain reaction.

^aThe 95% CI for GMEU were calculated based on the t-distribution of the log-transformed values, then back transformed to the original scale for presentation.

Table S7. Demographic Characteristics of Participants in PREVENT-19 Who Were HIV-Positive and HIV-Negative, and Seronegative/RT-PCR Negative to SARS-CoV-2 at Baseline, Who Received 2 Doses of NVX-CoV2373

Characteristic, n (%)	NVX-CoV2373 Recipients		
	HIV-Positive n = 119	HIV-Negative n = 536	Total N = 655
Age (years)			
Median (range)	53 (22–79)	46 (18–78)	48 (18–79)
Age group			
18 to 64 years	107 (89.9)	509 (95.0)	616 (94.0)
≥ 65 years	12 (10.1)	27 (5.0)	39 (6.0)
Sex			
Male	97 (81.5)	277 (51.7)	374 (57.0)
Female	22 (18.5)	259 (48.3)	281 (43.0)
Race			
White	61 (51.3)	445 (83.0)	506 (77.3)
Black or African American	44 (37.0)	52 (9.7)	96 (14.7)
American Indian or Alaska Native	2 (1.7)	2 (0.4)	4 (0.6)
Asian	3 (2.5)	25 (4.7)	28 (4.3)
Multiple	7 (5.9)	9 (1.7)	16 (2.4)

Characteristic, n (%)	NVX-CoV2373 Recipients		
	HIV-Positive	HIV-Negative	Total
	n = 119	n = 536	N = 655
Native Hawaiian or Other Pacific Islander	1 (0.8)	2 (0.4)	3 (0.5)
Not reported	1 (0.8)	1 (0.2)	2 (0.3)
Ethnicity			
Not Hispanic or Latino	91 (76.5)	446 (83.2)	537 (82.0)
Hispanic or Latino	27 (22.7)	89 (16.6)	116 (17.7)
Not reported or Unknown	1 (0.8)	1 (0.2)	2 (0.3)

Abbreviations: RT-PCR, reverse transcriptase polymerase chain reaction; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

Table S8. hACE2 Receptor Binding Inhibition Antibodies to SARS-CoV-2 S Protein at Day 0 (Baseline) and Day 35 (14 Days After Second Vaccination) in Adult Participants by Baseline Serostatus (PP-IMM-2 Analysis Set)

Parameter	Serologically/RT-PCR Negative		Serologically/RT-PCR Positive	
	NVX-CoV2373	Placebo	NVX-CoV2373	Placebo
	N = 717	N = 346	N = 42	N = 14
Day 0 (baseline)				
n1	717	346	42	14
GMT	5.2	5.0	18.2	25.4
95% CI ^a	5.0, 5.3	5.0, 5.0	12.8, 25.8	12.3, 52.6
Day 35				
n1	716	345	42	14
GMT	173.9	5.2	411.2	21.9
95% CI ^a	157.8, 191.7	5.0, 5.4	320.0, 528.3	11.2, 42.9

Abbreviations: CI, confidence interval; GMT, geometric mean titer; hACE2, human angiotensin-converting enzyme 2; n1, number of participants in the PP-IMM-2 Analysis Set with non-missing data at visit; PP-IMM-2, Per Protocol Immunogenicity 2; RT-PCR, reverse transcriptase polymerase chain reaction; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2

^aThe 95% CI for GMT were calculated based on the t-distribution of the log-transformed values, then back transformed to the original scale for presentation.

Table S9. 2019nCoV-301 Study Group (in Alphabetical Order of Institution Affiliation)

Affiliation/Funding*	Study Group	Location
México		
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Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán	Guillermo Miguel Ruiz-Palacios, MD	Mexico City, Mexico
Instituto Nacional de Salud Pública	Aurelio Cruz-Valdez, PhD, Janeth Pacheco-Flores, MD, Anyela Lara, MD, Secia Díaz-Miralrio	Cuernavaca, Mexico
PanAmerican Clinical Research México	María José Reyes Fentanes, MD, Jocelyn Zuleica Olmos Vega, MD, Daniela Pineda Méndez, MD, Karina Cano Martínez, MD, Winniberg Stephany Alvarez León	Querétaro, Mexico
PanAmerican Clinical Research México	Vida Veronica Ruiz Herrera, MD, Eduardo Gabriel Vázquez Saldaña, Laura Julia Camacho Choza, Karen Sofia Vega Orozco, Sandra Janeth Ortega Domínguez	Guadalajara, Mexico
Unidad de Atención Médica e Investigación en Salud (UNAMIS)	Jorge A. Chacón, MD, Juan J. Rivera, MD, Erika A. Cutz, MD, Maricruz E. Ortegón, MD, María I. Rivera, MD	Mérida, Mexico
United States and Puerto Rico		
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Accellacare	Rickey D. Manning, MD, James Wilson Hurst, MD, Rodney E. Sturgeon, MD, Paul H. Wakefield, MD, John A. Kirby, MD	Knoxville, TN
Accel Research Sites	James Andersen, MD, Szechekera Fearon, MSN, FNP-C, Rosa Negron, MD, Amy Medina, ADN, BS	Lakeland, FL
Accel Research Sites	Bruce Rankin, DO, John M. Hill, MD, Steven Shinn, MD, Vivek Rajasekhar, DO, Marshall Nash, MD	DeLand, FL
Achieve Clinical Research	Hayes Williams, MD, PhD, LaShondra Cade, Rhodna Fouts, Connie Moya	Birmingham, AL
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Alliance for Multispecialty Research	Michael Jacobs, MD, Kathleen Menasche, LPN, Vincent Mirkil, MD	Las Vegas, NV
Anaheim Clinical Trials	Peter J. Winkle, MD, Amina Z. Haggag, MD, Michelle Haynes, Marysol Villegas, Sabina Raja	Anaheim, CA
Atlanta Center for Medical Research	Robert Riesenberg, MD, Stanford Plavin, MD, Mark Lerman, MD, Leana Woodside, DNP, NP-C, Maria Johnson, MD	Atlanta, GA
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Cedar Crosse Research Center	Danny Sugimoto, MD, Jeffrey Dugas Sr., MD, Dolores Rijos, Sandra Shelton, Stephan Hong, MD	Chicago, IL
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