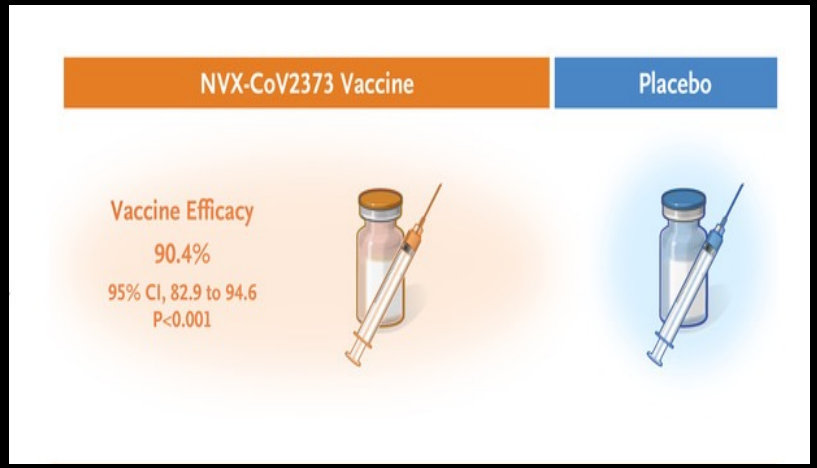
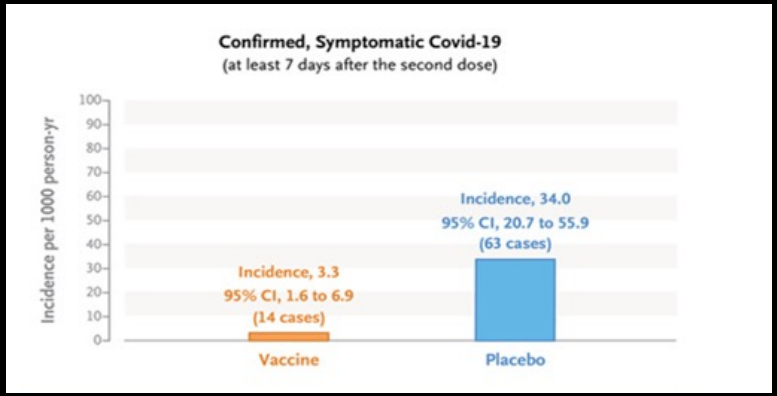
The NEW ENGLAND JOURNAL of MEDICINE

RESEARCH SUMMARY

Efficacy and Safety of NVX-CoV2373 in Adults in the United States and Mexico

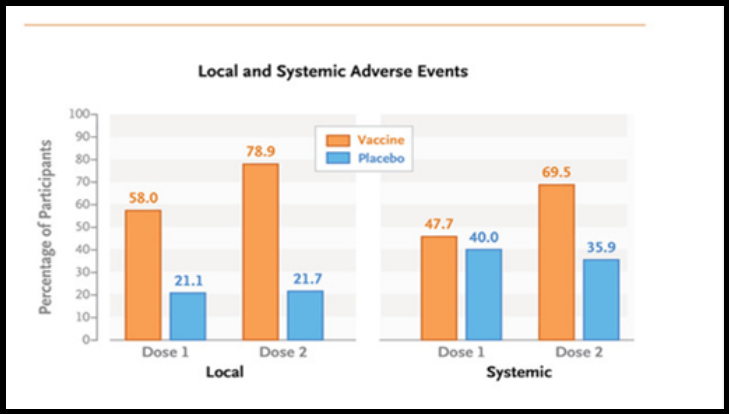
Dunkle LM et al. DOI: 10.1056/NEJMoa2116185





CONCLUSIONS

The NVX-CoV2373 vaccine was safe and efficacious for prevention of symptomatic Covid-19 in adults in the United States and Mexico.



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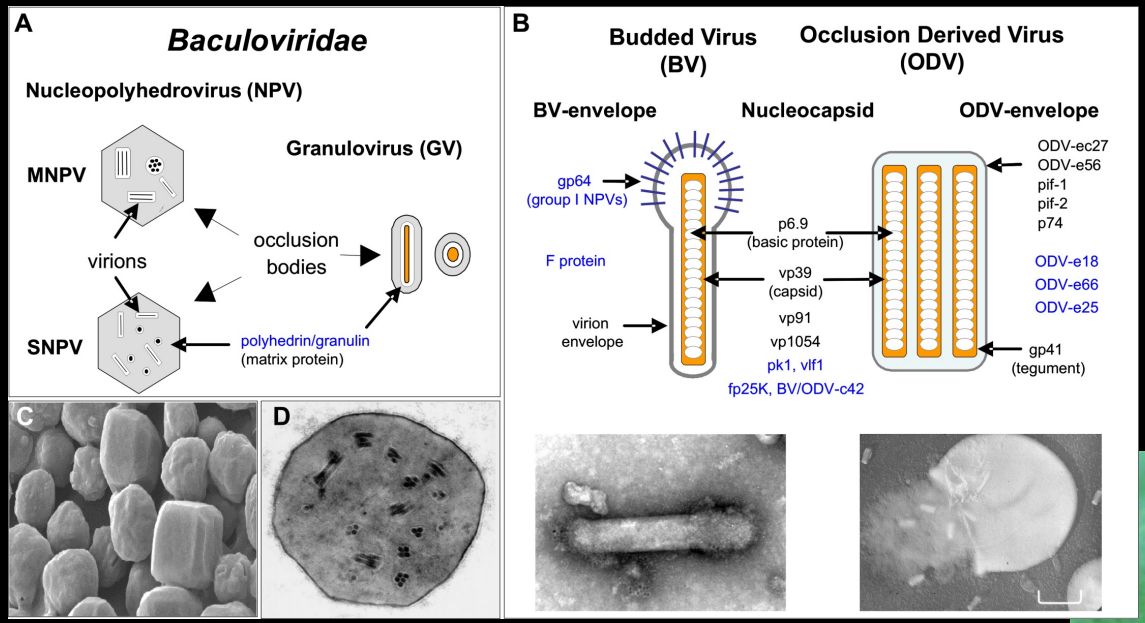
Harnessing nature…

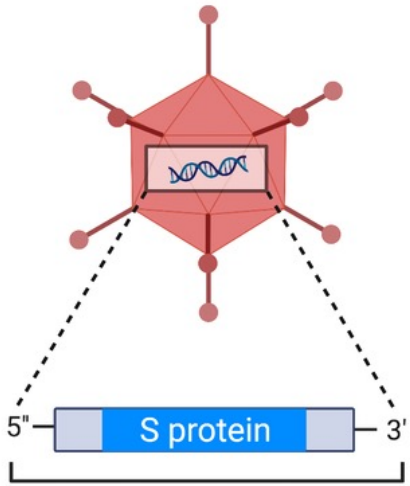


Spodoptera frugiperda (Sf9) or Fall Army Worm, host cells of which are infected with the baculavirus expression system to produce the spike protein antigen

Matrix-M uses *Quillaga saponaria* extract (Soapbark Tree) to boost the antigenic response

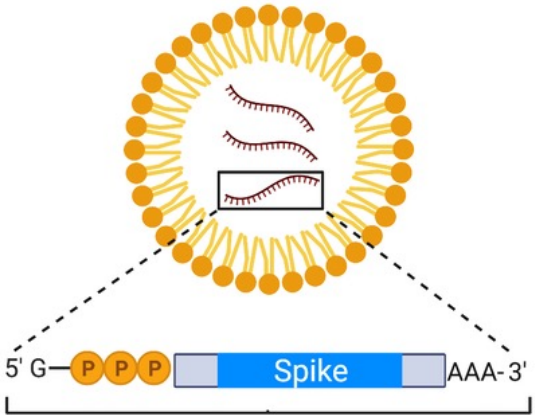
Schematic of Astra Zeneca, BioNTech/Pfizer and Novavax Vaccines

Vaccine: University of Oxford/ AstraZeneca



Platform: Adenovirus with gene for the SARS-CoV-2 spike (S) protein

BioNTech/Pfizer



Platform: lipid nanoparticle-encapsulated mRNA vaccines encoding Spike protein

Novavax

Platform: Synthetic nanoparticle coated with trimer spike protein. Matrix M used an immune-boosting adjuvant

Worldwide use of NVX-CoV2373

Demographic and Clinical Characteristics of the Participants at Baseline (Per-Protocol Efficacy Analysis Population).*

Table 1. Demographic and Clinical Characteristics of the Participants at Baseline (Per-Protocol Efficacy Analysis Population).*

Characteristic	NVX-CoV2373 (N=17,312)	Placebo (N=8140)	Total (N=25,452)
Median age (range) — yr	47.0 (18–95)	47.0 (18–90)	47.0 (18–95)
Age group — no. (%)			
18 to 64 yr	15,264 (88.2)	7,194 (88.4)	22,458 (88.2)
≥65 yr	2,048 (11.8)	946 (11.6)	2,994 (11.8)
Sex — no. (%)			
Male	9,050 (52.3)	4,131 (50.7)	13,181 (51.8)
Female	8,262 (47.7)	4,009 (49.3)	12,271 (48.2)
Race or ethnic group — no. (%)†			
White	13,140 (75.9)	6,184 (76.0)	19,324 (75.9)
Black or African American	1,893 (10.9)	900 (11.1)	2,798 (11.0)
American Indian or Alaska Native, including Mexican Natives	1,074 (6.2)	498 (6.1)	1,572 (6.2)
Asian	761 (4.4)	366 (4.5)	1,127 (4.4)
Multiple	293 (1.7)	132 (1.6)	425 (1.7)
Native Hawaiian or other Pacific Islander	47 (0.3)	10 (0.1)	57 (0.2)
Not reported	104 (0.6)	45 (0.6)	149 (0.6)
Hispanic or Latino			
No	13,538 (78.2)	6,379 (78.4)	19,917 (78.3)
Yes	3,733 (21.6)	1,751 (21.5)	5,484 (21.5)
Not reported	22 (0.1)	9 (0.1)	31 (0.1)
Unknown	19 (0.1)	1 (<0.1)	20 (0.1)
Overall high risk of Covid-19 — no. (%)‡			
Yes	16,493 (95.3)	7,737 (95.0)	24,230 (95.2)
No	819 (4.7)	403 (5.0)	1,222 (4.8)
High risk of severe Covid-19 — no. (%)§			
Yes	9,046 (52.3)	4,294 (52.8)	13,340 (52.4)
No	8,266 (47.7)	3,846 (47.2)	12,112 (47.6)
Coexisting conditions — no. (%)			
Any	8,117 (46.9)	3,910 (48.0)	12,027 (47.3)
Obesity	6,400 (37.0)	3,070 (37.7)	9,470 (37.2)
Chronic lung disease	2,442 (14.1)	1,218 (15.0)	3,660 (14.4)
Diabetes mellitus type 2	1,303 (7.5)	677 (8.3)	1,980 (7.8)
Cardiovascular disease	191 (1.1)	91 (1.1)	282 (1.1)
Chronic kidney disease	109 (0.6)	50 (0.6)	159 (0.6)
HIV infection — no. (%)	128 (0.7)	38 (0.5)	166 (0.7)
Country — no. (%)			
United States	16,294 (94.1)	7,638 (93.8)	23,932 (94.0)
Mexico	1,018 (5.9)	502 (6.2)	1,520 (6.0)

* The per-protocol efficacy analysis population included all participants who underwent randomization and received both doses as assigned, were seronegative for anti–SARS-CoV-2 nucleoprotein and had a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA RT-PCR–negative nasal swab at baseline, and did not have a censoring event at any time before 7 days after the second injection. HIV denotes human immunodeficiency virus.

† Race and ethnic group were reported by the participants.

‡ Participants at overall high risk included those 65 years of age or older and those of any age with chronic health conditions or an increased risk for Covid-19 because of work or living conditions.

§ Participants were classified as having a high risk of severe Covid-19 if they had one or more of the following coexisting conditions: obesity (defined as a body-mass index [the weight in kilograms divided by the square of the height in meters] of ≥30.0), chronic lung disease, diabetes mellitus type 2, cardiovascular disease, or chronic kidney disease.

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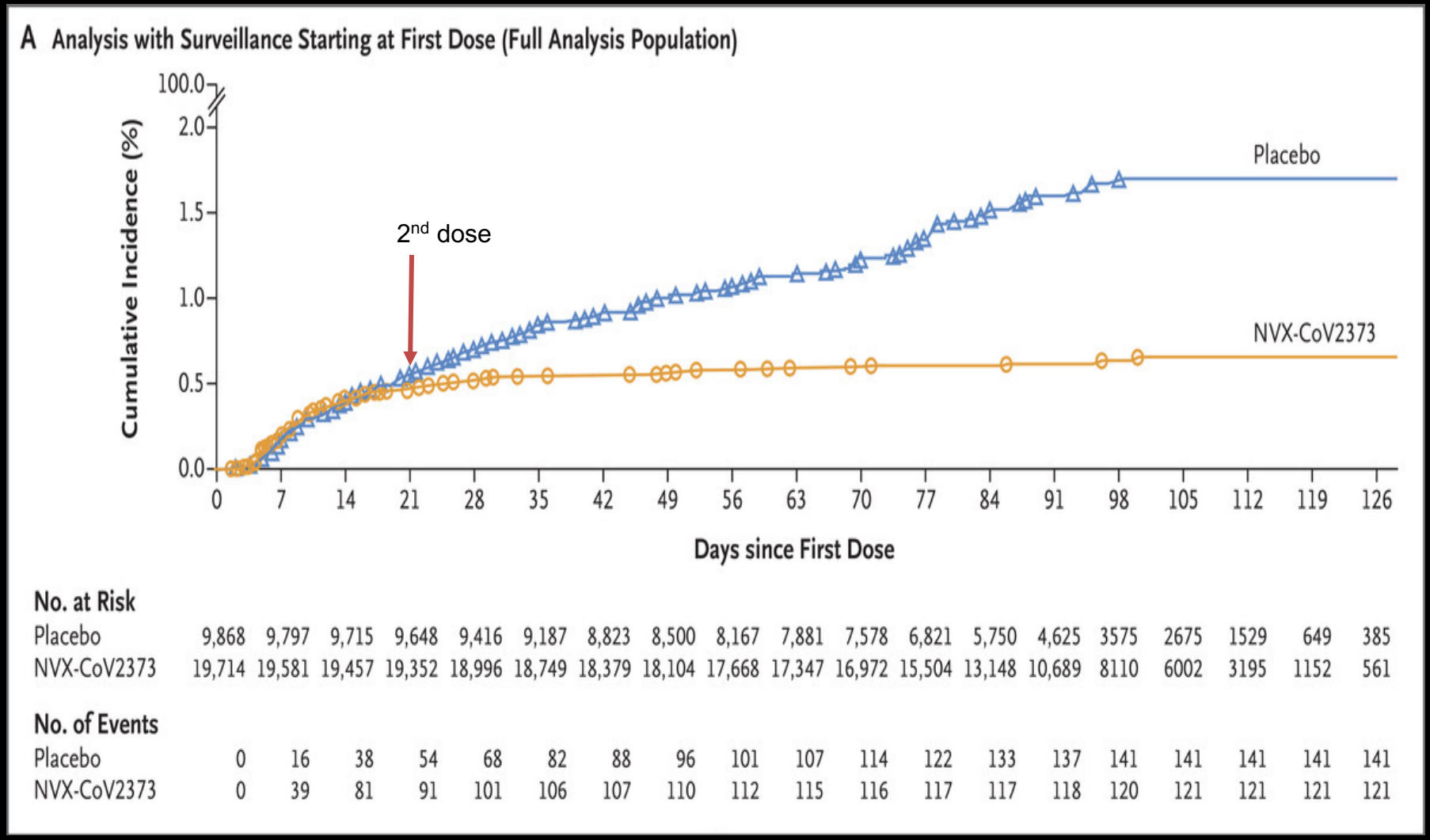
Overall Efficacy of NVX-CoV2373 against Covid-19.



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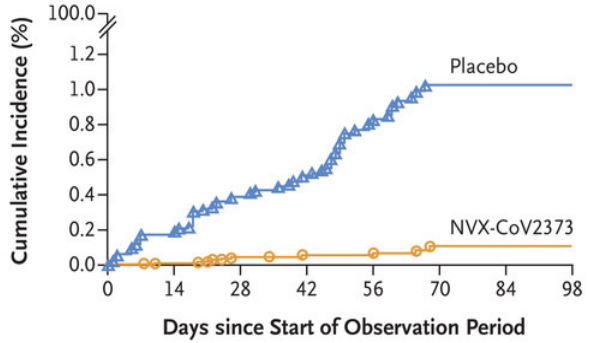
Overall Efficacy of NVX-CoV2373 against Covid-19.

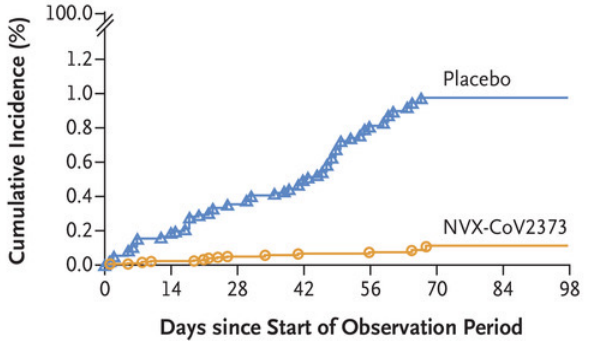
B Analysis with Surveillance Starting 7 Days after Second Dose (Per-Protocol Efficacy Analysis Population)



No. at Risk								
Placebo	8,140	7,619	6,989	6,349	4,627	2803	1055	220
NVX-CoV2373	17,312	16,782	16,166	15,330	11,458	6951	2447	379

No. of Events								
Placebo	0	16	30	38	56	63	63	63
NVX-CoV2373	0	2	7	10	11	14	14	14

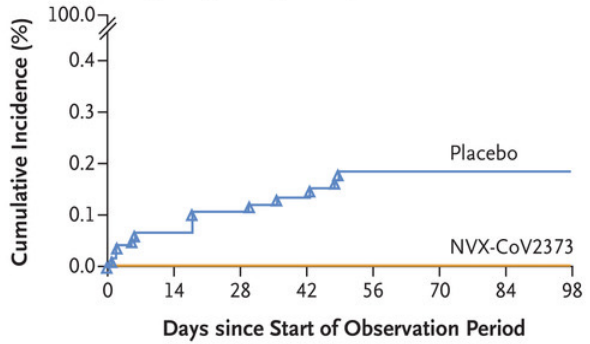
C Analysis with Surveillance Starting 7 Days after Second Dose (Full Analysis Population)



No. at Risk								
Placebo	9,144	8,635	8,016	7,343	5,366	3312	1320	323
NVX-CoV2373	18,584	18,055	17,450	16,557	12,401	7553	2737	463

No. of Events								
Placebo	0	17	31	42	62	69	69	69
NVX-CoV2373	0	4	9	12	13	16	16	16

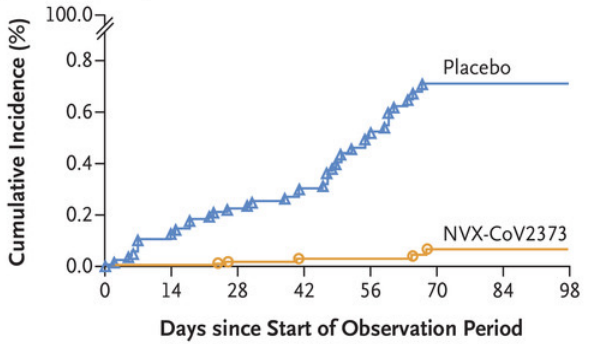
D Analysis of Covid-19 Due to Non-VOC and Non-VOI SARS-CoV-2 (Per-Protocol Efficacy Analysis Population)



No. at Risk								
Placebo	8,140	7,619	6,989	6,349	4,627	2803	1055	220
NVX-CoV2373	17,312	16,782	16,166	15,330	11,458	6951	2447	379

No. of Events								
Placebo	0	5	8	10	13	13	13	13
NVX-CoV2373	0	0	0	0	0	0	0	0

E Analysis of Covid-19 Due to VOC or VOI (Per-Protocol Efficacy Analysis Population)



No. at Risk								
Placebo	8,140	7,619	6,989	6,349	4,627	2803	1055	220
NVX-CoV2373	17,312	16,782	16,166	15,330	11,458	6951	2447	379

No. of Events								
Placebo	0	10	17	22	34	41	41	41
NVX-CoV2373	0	0	2	4	4	7	7	7

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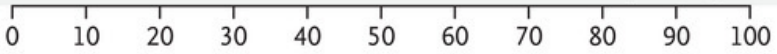
Vaccine Efficacy of NVX-CoV2373 in Specific Subgroups (Per-Protocol Efficacy Analysis Population).

Analysis Group	NVX-CoV2373	Placebo	Vaccine Efficacy (95% CI)
	no. of events/no. at risk (%)		
Per-protocol efficacy analysis population	14/17,312 (0.1)	63/8140 (0.8)	90.4 (82.9–94.6)
Full analysis population	16/18,584 (0.1)	69/9144 (0.8)	89.3 (81.6–93.8)
Subgroups			
Age of 18–64 yr	12/15,264 (0.1)	61/7194 (0.8)	91.5 (84.2–95.4)
Sex			
Male	5/9050 (0.1)	23/4131 (0.6)	90.9 (76.0–96.5)
Female	9/8262 (0.1)	40/4009 (1.0)	90.0 (79.3–95.1)
Race			
White	12/13,140 (0.1)	48/6184 (0.8)	89.4 (80.0–94.4)
Black	0/1893 (0.0)	7/905 (0.8)	100.0 (67.9–100.0)
Non-White	2/4068 (<0.1)	14/1911 (0.7)	93.6 (71.7–98.5)
Ethnic group			
Hispanic or Latino	8/3733 (0.2)	11/1751 (0.6)	67.3 (18.7–86.8)
Not Hispanic or Latino	6/13,538 (<0.1)	52/6379 (0.8)	95.1 (88.5–97.9)
Country: United States	14/16,294 (0.1)	62/7638 (0.8)	90.4 (82.8–94.6)
Coexisting conditions			
Yes	7/8109 (0.1)	34/3910 (0.9)	90.8 (79.2–95.9)
No	7/9203 (0.1)	29/4230 (0.7)	89.9 (77.1–95.6)
At high risk for Covid-19	13/16,493 (0.1)	62/7737 (0.8)	91.0 (83.6–95.0)



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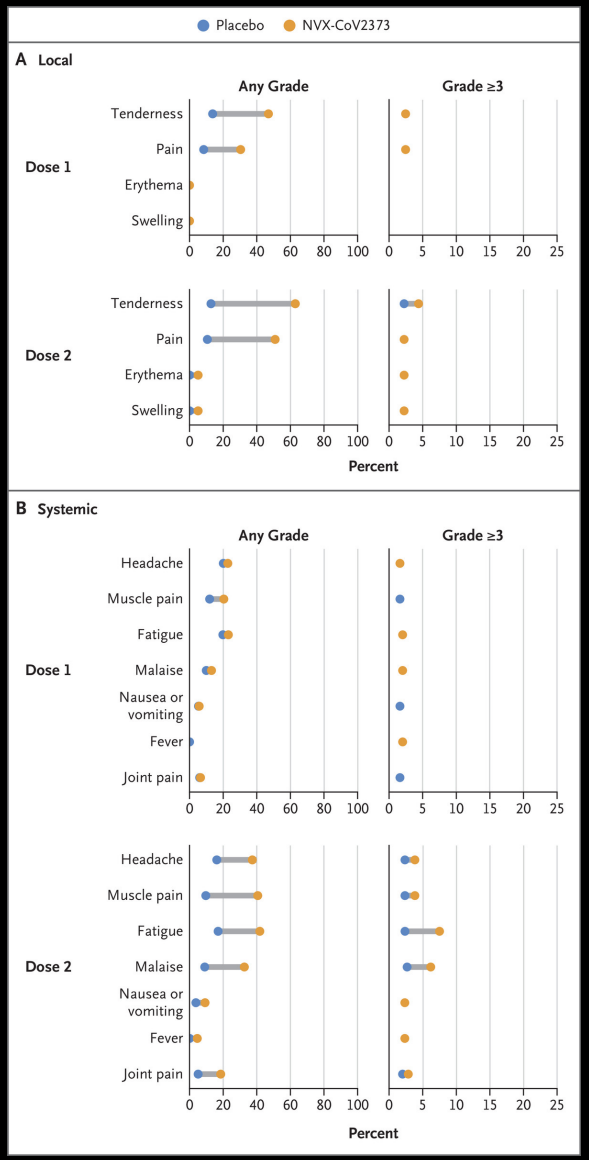
Solicited Local and Systemic Adverse Events (Safety Analysis Population).



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Limitations

During the trial, other COVID vaccines became available for older adults under EUA which reduced enrollment of adults 65 and older

Prior UK study had sufficient older adults and showed 88.9% VE in this age group

Unblinding requests were unbalanced between those who received the study vaccine and those who received the placebo

Variants arose during this trial that were not present during the trials with mRNA vaccines, with resulting VE comparable across variants, but the trial did not assess protection against delta or omicron

Conclusions

NVX-CoV2373 vaccine proved to be safe and effective at preventing symptomatic infection with PCR-confirmed SARS CoV-19

The vaccine platform differs from the currently available vaccines which may provide an acceptable choice for some people who have not yet received a COVID vaccine.

The vaccine is given in 2 doses, 21 days apart

Can be stored in a refrigerator at 2 – 8 deg C for up to 6 months