Supplementary Appendix

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This appendix has been provided by the authors to give readers additional information about the work.

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Objectives and End Points

Some secondary and exploratory objectives/end points (highlighted gray) were not addressed in this manuscript as they are still not yet available, including immunogenicity data and data from the period after blinded crossover. These results will be the subject of subsequent reports.

Table S1. Primary, Secondary, and Exploratory Objectives and End Points

Objectives	End Points
Primary:	**Primary:**
• To evaluate the efficacy of a two-dose regimen of SARS-CoV-2 rS adjuvanted with Matrix-M™ compared to placebo against RT-PCR-confirmed symptomatic Covid-19 illness diagnosed ≥7 days after completion of the second injection in the initial set of vaccinations of adult participants ≥18 years of age.	**Primary End Point:** • First episode of RT-PCR-positive mild, moderate, or severe Covid-19, where severity is defined as: **Mild Covid-19 (≥1 of the following):** • Fever (defined by subjective or objective measure, regardless of use of anti-pyretic medications) • New onset cough • ≥2 additional Covid-19 symptoms: o New onset or worsening of shortness of breath or difficulty breathing compared to baseline. o New onset fatigue. o New onset generalized muscle or body aches. o New onset headache. o New loss of taste or smell. o Acute onset of sore throat, congestion, or runny nose. o New onset nausea, vomiting, or diarrhea. **OR Moderate Covid-19 (≥1 of the following):** • High fever (≥38.4°C) for ≥3 days (regardless of use of anti-pyretic medications, need not be contiguous days). • Any evidence of significant LRTI: o Shortness of breath (or breathlessness or difficulty breathing) with or without exertion (greater than baseline). o Tachypnea: 24 to 29 breaths per minute at rest. o SpO_2: 94% to 95% on room air. o Abnormal chest X-ray or chest CT consistent with pneumonia or LRTI. • Adventitious sounds on lung auscultation (e.g., crackles/rales, wheeze, rhonchi, pleural rub, stridor). **OR Severe Covid-19 (≥1 of the following):** • Tachypnea: ≥30 breaths per minute at rest. • Resting heart rate ≥125 beats per minute. • SpO_2: ≤93% on room air or PaO_2/FiO_2 <300 mmHg. • High flow O_2 therapy or NIV/NIPPV (e.g., CPAP or BiPAP). • Mechanical ventilation or ECMO. • One or more major organ system dysfunction or failure to be defined by diagnostic testing/clinical syndrome/interventions, including any of the following: o Acute respiratory failure, including ARDS. o Acute renal failure. o Acute hepatic failure. o Acute right or left heart failure.

Objectives	End Points
	○ Septic or cardiogenic shock (with shock defined as SBP <90 mm Hg OR DBP <60 mm Hg). ○ Acute stroke (ischemic or hemorrhagic). ○ Acute thrombotic event: AMI, DVT, PE. ○ Requirement for: vasopressors, systemic corticosteroids, or hemodialysis. • Admission to an ICU. • Death.
Key Secondary Objective:	**Key Secondary End Point:**
• To evaluate the efficacy of a two-dose regimen of SARS-CoV-2 rS adjuvanted with Matrix-M™ compared to placebo against RT-PCR-confirmed symptomatic Covid-19 illness due to a SARS-CoV-2 variant not considered as a "variant of concern / interest" according to the CDC Variants Classification, diagnosed ≥7 days after completion of the second injection in the initial set of vaccinations of adult participants ≥18 years of age.	• First episode of RT-PCR-positive Covid-19, as defined under the primary end point, shown by gene sequencing to represent a variant not considered as a "variant of concern / interest" according to the CDC Variants Classification.
Other Secondary Objectives:	**Other Secondary End Points:**
• To evaluate the efficacy of a two-dose regimen of SARS-CoV-2 rS adjuvanted with Matrix-M™ compared to placebo against RT-PCR-confirmed moderate-to-severely symptomatic Covid-19 illness diagnosed ≥7 days after completion of the second vaccination in the initial set of vaccinations of adult participants ≥18 years of age. • To assess VE against ANY symptomatic SARS-CoV-2 infection. • To assess VE according to race and ethnicity. • To assess VE in high-risk adults versus non-high-risk adults (high-risk is defined by age ≥65 years with or without comorbidities or age <65 years **with** comorbidities [e.g., obesity (BMI >30 kg/m^2), chronic kidney or lung disease, cardiovascular disease, and diabetes mellitus type 2] and/or by life circumstance [living or working conditions involving known frequent exposure to SARS-CoV-2 or to densely populated circumstances (e.g., factory or meat packing plants, essential retail workers, etc.)]). • To assess the durability of vaccine efficacy (measured by all defined efficacy end points) in initial active vaccine recipients versus crossover (delayed) active vaccine recipients.* • To describe the humoral immune response to vaccine in terms of neutralizing antibody to SARS-CoV-2 for all Immunogenicity Population Participants, and for subsets with and without prior SARS-CoV-2 exposure determined by detectable anti-NP antibodies at baseline.* • To assess the immune response to vaccine by IgG antibody to SARS-CoV-2 S protein and hACE2 inhibiting antibodies at Day 35 and later for all Immunogenicity Population participants, and for subsets with and without prior SARS-CoV-2 exposure determined by detectable anti-NP antibodies at baseline.* • To assess the durability of immune response (IgG antibody to SARS-CoV-2 S protein, hACE2	• First episode of RT-PCR-positive moderate or severe Covid-19, as defined under the primary end point. • ANY symptomatic SARS-CoV-2 infection, defined as: RT-PCR-positive nasal swab and ≥1 of any of the following symptoms: ○ Fever. ○ New onset cough. ○ New onset or worsening of shortness of breath or difficulty breathing compared to baseline. ○ New onset fatigue. ○ New onset generalized muscle or body aches. ○ New onset headache. ○ New loss of taste or smell. ○ Acute onset of sore throat, congestion, or runny nose. ○ New onset nausea, vomiting, or diarrhea. • Neutralizing antibody titers from Immunogenicity Population at Days 0, 35, and immediately prior to administration of the crossover set of vaccinations.* • Serum IgG levels to SARS-CoV-2 S protein, hACE2 inhibition titers from Immunogenicity Population at Days 0, 35, and immediately prior to administration of the crossover set of vaccinations.* • Serum IgG levels to SARS-CoV-2 S protein, MN, and hACE2 inhibition titers from Immunogenicity Population at Months 12, 18, and 24.* • Description of course, treatment, and severity of Covid-19 reported after a RT-PCR-confirmed case via the Endpoint Form. • Reactogenicity incidence and severity (mild, moderate, or severe) recorded by all participants on their eDiary on days of vaccination and subsequent 6 days (total 7 days after each vaccine injection in the initial set of vaccinations). ○ Reactogenicity end points include injection site reactions: ▪ Pain. ▪ Tenderness. ▪ Erythema.

Objectives	End Points
inhibition, and MN) at 12, 18 and 24 months of study in all Immunogenicity Population participants, and for subsets with and without detectable anti-NP antibodies at baseline or prior to crossover set of vaccinations. • To describe and compare the safety experience for the vaccine versus placebo in adult participants ≥18 years of age based on solicited short-term reactogenicity by toxicity grade for 7 days following each vaccination (Days 0 and 21) after the initial set of vaccinations. • To assess overall safety through 49 days (28 days after second injection of each set of vaccinations [initial and crossover]) and to compare vaccine versus placebo for all unsolicited AEs and MAAEs. • To assess the frequency and severity of MAAEs attributed to vaccine, AESIs, or SAEs through the EoS and to compare vaccine versus placebo after each set of vaccinations (initial and crossover).* • To assess all-cause mortality in vaccine versus placebo recipients after each set of vaccinations (initial and crossover).* • To describe the severity and course of Covid-19 in vaccine versus placebo recipients in terms of healthcare requirements, utilization, and medical assessments after each set of vaccinations (initial and crossover).* • To assess the proportion of participants (vaccine versus placebo recipients) with SARS-CoV-2 infection determined by anti-SARS-CoV-2 NP antibodies, including specifically asymptomatic infection, across the 2 years of study follow-up.* • To assess the VE against SARS-CoV-2 infection determined by anti-SARS-CoV-2 NP antibodies, regardless of whether the infection was symptomatic.* • To assess in a subset of participants the immunogenicity of a new lot of SARS-CoV-2 rS with Matrix-M™ adjuvant in comparison to the lot utilized in the initial set of vaccinations (i.e., immunobridging).*	▪ Swelling/induration. ○ Systemic reactions: ▪ Fever. ▪ Malaise. ▪ Fatigue. ▪ Arthralgia. ▪ Myalgia. ▪ Headache. ▪ Nausea/vomiting. • Incidence and severity of MAAEs through 49 days, i.e., 28 days after second injection of each set of vaccinations (initial and crossover). • Incidence and severity of unsolicited AEs through 49 days, i.e., 28 days after second injection of each set of vaccinations (initial and crossover). • Incidence and severity of MAAEs attributed to study vaccine, SAEs, and AESIs through Month 12.* • Incidence and severity of SAEs, MAAEs attributed to study vaccine and AESIs during Month 12 through Month 24 or the EoS.* • Death due to any cause.* • Data points to be collected for healthcare requirements, utilization, and medical assessments from participants who become ill on study will be defined in a separate substudy protocol.* • Antibodies to SARS-CoV-2 NP at Days 0 and 35, immediately prior to administration of the crossover set of vaccinations, and at Months 12, 18, and 24 will be used to determine natural infection and to determine the incidence of asymptomatic infection acquired during study follow-up.* • Antibodies to SARS-CoV-2 NP, regardless of whether the infection was symptomatic.* • IgG antibodies to SARS-CoV-2 rS at approximately 35 days after the first crossover vaccination in approximately 300 active vaccine recipients 18 to ≤64 years of age enrolled at selected study sites.* • Neutralizing antibody response at Day 35 for all adolescent participants seronegative to anti-SARS-CoV-2 NP antibodies at baseline, compared with that observed in seronegative adult participants 18 to <26 years of age from the Adult Main Study (Immunogenicity Population participants before crossover).* • Antibodies to SARS-CoV-2 NP, regardless of whether the infection was symptomatic.*
Exploratory Objectives:	**Exploratory End Points:**
• To evaluate the efficacy of study vaccine compared to placebo against RT-PCR-confirmed symptomatic Covid-19 illness due to a SARS-CoV-2 variant considered as a "variant of concern / interest" according to the CDC Variants Classification, diagnosed ≥7 days after completion of the second vaccination in the initial set of vaccinations of adult participants ≥18 years of age. • To assess cell-mediated response: ○ Th1 or Th2 predominance after initial set of vaccinations.*	• First episode of RT-PCR-positive Covid-19, as defined under the primary end point, shown by gene sequencing to represent a "variant of concern / interest" according to the CDC Variants Classification. • Th1 or Th2 responses, e.g., IL-2, IL-4, IL-5, IL-13, TNF-α, IFN-γ in whole blood and/or harvested PBMCs prior to and on Day 35 after the initial set of vaccinations.* • Serum samples from a designated subset of up to approximately 4500 Immunogenicity Population participants to be transferred to NIAID for testing and analysis to determine correlates of risk and protection.

Objectives	End Points
• To contribute to a larger cross-study NIH effort to define correlates of risk and protection against SARS-CoV-2 infection and disease.*	End points will be described in a separate statistical analysis plan developed by external statistics groups (e.g., CoVPN, OWS).*
• To assess impact of vaccination on nasal viral load in nasal swabs of participants who develop symptoms of possible Covid-19.*	• Quantitative RT-PCR tests may be performed on nasal swabs collected from this trial to assess whether vaccination impacts viral shedding.*
• To assess impact of vaccination on asymptomatic SARS-CoV-2 RT-PCR positivity and viral load at the time of the crossover set of vaccinations.*	• Quantitative RT-PCR tests performed on nasal swabs collected immediately prior to administration of blinded crossover vaccination to assess impact of initial vaccination on frequency of asymptomatic SARS-CoV-2 infection and level of viral shedding.*
• To describe sequences of the genetic material from SARS-CoV-2 viruses detected in Covid-19 cases to evaluate possible viral mutations that may be associated with breakthrough infections.*	• Next-generation sequencing of viral genomes detected in nasal swabs tested by RT-PCR to describe the genetic evolution of circulating SARS-CoV-2 strains during the conduct of the study.*

Abbreviations: AESI = adverse event of special interest; AMI = acute myocardial infarction; ARDS = acute respiratory distress syndrome; BiPAP = bilevel positive airway pressure; BMI = body mass index; CDC = Centers for Disease Control and Prevention; Covid-19 = coronavirus disease 2019; CoVPN = Covid-19 Prevention Network; CPAP = continuous positive airway pressure; CT = computed tomography; DBP = diastolic blood pressure; DVT = deep vein thrombosis; ECMO = extracorporeal membrane oxygenation; eDiary = electronic patient-reported outcome diary; EoS = end of study; FiO_2 = fraction of inspired oxygen; hACE2 = human angiotensin-converting enzyme 2; ICU = intensive care unit; IgG = immunoglobulin G; IFN-γ = interferon gamma; IL = interleukin; LRTI = lower respiratory tract infection; MAAE = medically attended adverse event; MN = microneutralization; NIAID = National Institute of Allergy and Infectious Diseases; NIH = National Institutes of Health; NP = nucleocapsid; NIPPV = non-invasive positive pressure ventilation; NIV = non-invasive ventilation; O_2 = oxygen; OWS = Operation Warp Speed; PaO_2 = partial pressure of oxygen; PBMC = peripheral blood mononuclear cell; RT-PCR = reverse transcriptase-polymerase chain reaction; PE = pulmonary embolism; SAE = serious adverse event; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine; SBP = systolic blood pressure; SpO_2, oxygen saturation; Th1 = type 1 T helper; Th2 = type 2 T helper; TNF-α = tumor necrosis factor alpha; VE = vaccine efficacy.

* Objectives/end points not addressed in the interim report due to incompleteness or yet unavailable data are noted in the table; this includes immunogenicity data and data from the period after blinded crossover.

Supplemental Methods

Recruitment Strategy

At least 25% of the study population was originally intended to be in the ≥65 years age group; however, availability of vaccines under the Emergency Use Authorization (EUA) during the first weeks of the study required the reprioritization of this population for public health and ethical reasons. Prioritization was given to enrollment of individuals at overall high risk for Covid-19, e.g., high risk for acquisition of Covid-19 of any severity due to living circumstances common to the Black/African American or American Indian/Alaska Native communities (including Native Americans of Mexican origin), Hispanic of Latino ethnicity, or other living or working conditions involving known frequent exposure to SARS-CoV-2 (e.g., factory or meat packing plants, essential retail workers, etc.), or at high risk of developing severe Covid-19 complications by virtue of comorbid conditions (e.g., obesity [BMI >30 kg/m^2], chronic kidney or lung disease, cardiovascular disease, and diabetes mellitus type 2).

Safety Assessments

Following collection of sufficient safety data to support application for EUA, i.e., 2 months' duration of safety follow-up, participants were scheduled for administration of 2 injections of the alternate study material 21 days apart ("blinded crossover"). That is, initial recipients of placebo did receive SARS-CoV-2 rS with Matrix-M™ adjuvant and initial recipients of SARS-CoV-2 rS with Matrix-M™ adjuvant did receive placebo. The same procedure for vaccine administration followed for the initial set of vaccinations was followed at the time of the blinded crossover to ensure that the integrity of the blinded study was maintained.

Solicited AEs of reactogenicity after the initial series of vaccinations was collected via participant reporting in the eDiary utilizing a smartphone application. All participants were trained on the use of these applications, and smartphone devices were provided for those participants who needed them at the initiation of their participation in the study (Day 0).

Safety assessments included collection of participant-recorded solicited (local and systemic reactogenicity) events through 7 days following each injection in the initial set of vaccinations collected via eDiary. Unsolicited AEs and MAAEs were collected through 49 days, i.e., 28 days after second injection of the initial and crossover sets of vaccinations. MAAEs attributed to

vaccine, AESIs, SAEs, and investigator-assessed targeted physical examination findings, including vital sign measurements, will be collected through Month 12. Safety follow-up phone calls will be conducted at 3 and 6 months (±30 days) post-crossover to collect MAAEs attributed to vaccine, AESIs, and SAEs in all participants who received crossover vaccinations.

Safety Monitoring

Safety was monitored routinely by the Sponsor physicians and routinely by the 2019nCoV-301 Protocol Safety Review Team (PSRT). A centralized DSMB was established in collaboration with NIH, NIAID, Biomedical Advanced Research and Development Authority (BARDA), and Novavax according to the charter dictated by the participating groups. This group reviewed interim unblinded data periodically, made recommendations with respect to safety and emerging efficacy and needed changes to study design. The DSMB was to be informed immediately by the study unblinded statistician if the prespecified stopping boundary was met, indicating that the vaccine caused harm by increasing the rate of mild, moderate, or severe Covid-19. In addition, the DSMB monitored the study for high vaccine efficacy or for futility to detect vaccine activity.

Prospective Surveillance of Covid-19

For prospective surveillance, participants were provided with an oral thermometer on Day 0 and instructed to monitor their body temperature daily throughout the first 12 months of the study and to record temperature and any other relevant symptoms daily in their eDiary.

When fever or other specified symptoms were reported in the eDiary for at least 2 consecutive days for the same symptom, participants were directed via the eDiary to begin nasal self-swabbing at home for RT-PCR testing for a total of 3 days and to initiate daily completion of the InFLUenza Patient-Reported Outcome (FLU-PRO) symptom reporting instrument for 10 days after Covid-19 symptom onset or until the participant experienced 2 consecutive asymptomatic days. Participants were instructed at their enrollment visit on the methods of nasal self-swabbing for Covid-19 and completion of the FLU-PRO symptom reporting instrument. The self-swabs to be obtained by the participant were to be maintained according to directions provided in the 3-swab kit, and the designated courier was to be contacted to pick up the kit for shipping to the central laboratory, as directed.

In addition, the eDiary did alert the study site to contact the participant to schedule the in-person Acute Illness Visit for medical evaluation (to include oxygen [O_2] saturation and respiratory rate) and medically attended nasal swab. Participants were provided with a pulse oximeter and instructions for measuring and recording their O_2 saturation daily at home during their illness. Active surveillance for Covid-19 will continue after the blinded crossover through the first 12 months of study. Passive surveillance of safety and efficacy via remote contacts or the scheduled visits will continue during Months 12 to 24.

Study participants whose home nasal self-swab and/or medically attended nasal swabs were confirmed at the central laboratory to be RT-PCR-positive for SARS-CoV-2 at the Acute Illness Visit were contacted by the study site to arrange a Convalescent Visit. The Convalescent Visit was to occur approximately 1 month (or as soon thereafter, as feasible) after the onset of the RT-PCR-confirmed case of Covid-19 at the Acute Illness Visit to assess status of AEs, record the clinical course of the disease on the End Point Form and obtain a blood sample for convalescent serologic testing.

Covid-19 End Point Assessment

To ensure the quality and accuracy of investigator-recorded end point assessments collected on the Endpoint Assessment eCRF page, programmatic checking was performed prior to the data extraction for analysis. The algorithms and the data sources to be used for programming were determined and documented prior to unblinding. Using data elements relevant to the end point definition and captured in the eCRF, programmatic determination of potential end points and associated start date and severity were performed. Data elements used included the participant reported daily symptoms collected on the Daily Illness Symptoms Report eDiary, RT-PCR results by the central laboratory from participant self-swabbing, RT-PCR results by the central laboratory from the swab collected at the Acute Illness Visit, pulse oximeter readings reported by study participants, and pulse oximeter readings collected at the Acute Illness Visit. Disease episodes were constructed programmatically, including date of initial symptoms, date of positive RT-PCR test result, and preliminary severity based on symptoms reported and pulse oximeter readings. The programmatically determined end points were compared to the data collected on the Endpoint Assessment eCRF. Discrepancies such as missing or difference in date that illness started or difference in severity rating prompted Data Management to issue queries to the

investigators. The Endpoint Assessment eCRF data, along with the official study RT-PCR results from the University of Washington, Seattle, WA, were used for analysis of the efficacy end points.

Potentially severe cases of symptomatic RT-PCR-positive Covid-19 were reviewed by an external Independent Endpoint Review Committee (ERC) established by the sponsor. The ERC consisted of physicians who have clinical and research experience (e.g., medical review and/or clinical trial experience) in infectious diseases. The committee's structure, responsibilities, and operation were specified within a charter. Potentially severe cases included Covid-19 reported as SAEs, programmatically identified end points consisting of at least 1 pulse oximeter reading ≤93%, and episodes identified as severe on the Endpoint Assessment eCRF. For pulse oximeter readings, when both participant-recorded values and site collected values were present, both were presented, but the site readings were given preference as to clinical utility. Participant profiles (as outlined in the charter) were provided to the committee members for review according to the process outlined in the charter. These participant profiles included demographics, medical history, AEs, concomitant medications, reported daily symptoms, and the Endpoint Assessment eCRF. The external reviewers documented the criteria used for their clinical review of the cases.

The results of the review were to confirm the case as severe or rule that the case was not severe. The outcome of the review for each case was stored in an electronic medical review system. A file was exported from the system and provided to the Biostatistics group for use in analysis. Cases that were ruled as not severe by the committee despite an investigator-entered severe grading were further reviewed and documented by Novavax clinician(s) prior to unblinding to determine the severity to use in analysis. Cases that were ruled as severe by the ERC but not severe by the investigator were analyzed as severe in the analysis.

Nasal Swabs for Viral Detection

Nasal swabs of the anterior nares were obtained at the study site on Day 0 (prior to study vaccination), at the Acute Illness Visit, and at the first crossover vaccination visit.

Participants who experienced an SAE of severe Covid-19 any time after Day 0 were to have a nasal swab obtained (by site personnel or other healthcare personnel) to be sent by the study site

to the study central laboratory. Such a swab, if obtained, constituted the medically attended nasal swab recorded on the Acute Illness Visit form.

Participants in the adult portion of the trial were instructed at their enrollment visit on the method of self-swabbing for Covid-19 and procedure for arranging transport of swabs to the central laboratory. Quantitative RT-PCR was performed on RT-PCR-positive swabs using the Abbott RealTime RT-PCR to assess viral load and sequencing of viral genetic material detected in nasal swab RT-PCR testing to evaluate viral mutations.

SARS-CoV-2 RT-PCR Testing

The real-time reverse transcriptase-polymerase chain reaction (RT-PCR) test being used is the Abbott RealTime SARS-CoV-2 Assay, which was granted EUA by the US Food and Drug Administration (FDA) on March 18, 2020 (https://www.fda.gov/media/136255/download). The testing was performed at the University of Washington. The validation and verification of the Abbott RealTime SARS-CoV-2 Assay analytical and clinical performance has been published.[1] Dry swabs were used and have been validated for this assay with storage at 2-8°C for up to 7 days and then frozen at -80°C. Once the sample is received at the University of Washington, the dry swabs are eluted into Roswell Park Memorial Institute (RPMI) +2% fetal bovine serum (FBS) or phosphate buffered saline (PBS) prior to testing. The University of Washington conducted an analysis validating and verifying the performance of the Abbott RealTime SARS-CoV-2 Assay with varying viral dilutions. The outcome of the analysis was published elsewhere.[2]

Whole-Genome Sequencing (WGS) and Clade/Lineage Assignment

The key secondary end point of the trial was the first episode of RT-PCR-positive, symptomatic Covid-19 due to strain shown by gene sequencing to represent a variant not considered as a variant of concern (VOC) or variant of interest (VOI) according to the Centers for Disease Control and Prevention (CDC) SARS-CoV-2 Variant Classifications and Definitions,[3] starting at least 7 days post-vaccination 2 in the initial vaccination period. Baseline RT-PCR-positive samples as well as RT-PCR-positive samples from self-swabbing or the Acute Illness Visit with enough viral load were sent to the University of Washington Virology Laboratory for WGS,

using methodology described elsewhere.[4] In case of multiple RT-PCR-positive samples for a given symptomatic episode, that with the highest viral load was chosen for sequencing.

Sequencing analysis included viral clade/lineage assignment using both the Nextstrain clade label system (https://nextstrain.org/blog/2021-01-06-updated-SARS-CoV-2-clade-naming) and the PANGO lineages designation system (https://cov-lineages.org/), and identification as a VOC/VOI/High Consequence, per the CDC (https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html). Evaluation of SARS-CoV-2 infection or disease was available by site and/or geographic region. The classification of variants was conducted by the University of Washington Virology Laboratory and provided for analysis.

Analysis Populations

There were 6 main analysis sets used in this trial:

- The **Intent-to-Treat (ITT) Analysis Set** included all participants who were randomized, regardless of protocol violations or missing data. The ITT analysis set was used for participant disposition summaries and were analyzed according to the treatment arm to which the participant was randomized.
- The **Full Analysis Set (FAS)** included all participants who were randomized and received at least 1 dose of study vaccine/placebo, regardless of protocol violations or missing data. Participants who were unblinded with an intention to receive other Covid-19 vaccines were censored at the time of unblinding. The FAS population was analyzed according to the treatment group to which participants were randomized. The FAS were used for supportive analyses. When the efficacy end points were analyzed using FAS, baseline SARS-CoV-2 seropositivity or nasal swab RT-PCR-positivity was ignored.
- The **Safety Analysis Set** included all randomized participants who received at least 1 dose of study vaccine/placebo. Participants in the Safety Analysis Set were analyzed according to the treatment actually received. In cases where information is available that indicated that a participant received both active vaccine and placebo during the initial vaccination series, the participant was analyzed as part of the active group.

- The **Per-Protocol Efficacy (PP-EFF) Analysis Set** included all participants who received the full prescribed regimen of trial vaccine and had no major protocol deviations that occurred before the first Covid-19 positive episode (i.e., participant was censored at the time of the protocol deviation) and were determined to affect the efficacy outcomes, including baseline SARS-CoV-2 seropositivity or nasal swab RT-PCR -positivity. Participants who were unblinded with an intention to receive other Covid-19 vaccines were censored at the time of unblinding. Although the study enrolled participants regardless of SARS-CoV-2 serologic status at the time of initial vaccination, any participants with confirmed infection or prior infection due to SARS-CoV-2 at baseline, by nasal swab RT-PCR or serology (assessed by anti-nucleocapsid [anti-NP]), were excluded from the PP-EFF population. PP-EFF was the primary set for all efficacy end points.

- A second **PP-EFF (PP-EFF-2) Analysis Set** was defined to allow evaluation of baseline serostatus analysis's impact on vaccine efficacy (VE). The PP-EFF-2 Analysis Set followed the same method described in the PP-EFF population with the exception that it included all participants regardless of baseline serostatus (anti-NP serology) or baseline virological status (RT-PCR).

Statistical Method for Efficacy End Points

The VE is defined as VE (%) = (1 – RR) × 100, where RR = relative risk of incidence rates between the 2 trial vaccine groups (SARS-CoV-2 rS / placebo). The RR was estimated by exponentiating the treatment group coefficient from a Poisson regression analysis with robust error variance.[5] The age strata was included in the model as a covariate. To assess incidence rates rather than absolute counts of cases, accounting for differences in follow-up times starting at 7 days after the second vaccination among participants, an offset was utilized in the Poisson regression. When a zero was reported in one of the treatment groups compared (e.g., Black or African Americans) or there were fewer than 5 cases total between groups, the exact conditional method was used instead. A two-sided, 95% confidence interval (CI) was constructed around the estimate.

A super superiority of the vaccine efficacy at each analysis was used to determine the success of the primary end point. A hypothesis test with a one-sided Type I error of 2.5% was conducted with the following hypotheses:

H_0: VE $\leq$0.30 (RR $\geq$0.70)

H_1: VE >0.30 (RR <0.70)

Rejection of the null hypothesis demonstrates a statistically significant VE with a lower bound of CI >30%. In order to be considered for EUA by the FDA, a vaccine must show super superiority where there is a minimum VE of 50% and a lower bound of two-sided 95% confidence bound of at least 30%. Based upon the number of primary efficacy end points planned for analysis, a lower bound of more than 30% corresponds with a VE point estimate of at least 50%.[6]

The RR and its CI was estimated using Poisson regression with robust error variance.[5] The generalized linear model with unstructured correlation matrix (robust error variances) was used. The explanatory variables in the model included the trial vaccine group. The dependent variable was the incidence rate of the end point of interest. The robust error variances were estimated using repeated statement and the participant identifier. The age strata were included in the model as a covariate. To account for the censoring in the analysis, the offset was defined as the natural log of the time from the start of follow-up (7 days post-second vaccination) to the outcome of interest or to the end of study in addition to censoring described in the analysis set definitions. Poisson distribution was used with a logarithmic link function. In the case where there were zero end points for one of the vaccine groups or the total number of end points in both treatment groups combined is less than 5, a Poisson model was substituted with an exact conditional binomial method using the Clopper-Pearson method. This method conditions on the total number of events across the treatment groups where the number of events in the active group are generated from a single binomial distribution. The point estimate form this single binomial distribution and the corresponding confidence intervals constructed using the Clopper-Pearson method were transformed back to relative risks.

A Cox proportional hazards model with the age strata as a covariate was also developed as a supportive analysis to the Poisson regression. The model followed the same explanatory and

dependent variables as the Poisson model and censored participants based on their follow-up time available.

Interim analysis

In early versions of the Protocol, two formal interim analyses of efficacy and futility for review by the independent DSMB, as described in the DSMB Charter, were planned to be conducted based on the accumulation of approximately 50% (n = 72) and 75% (n = 108) of the total anticipated primary endpoints. The interim analyses were to be performed by an unblinded Biostatistics and Programming team and reviewed by the independent DSMB that would make recommendations with regard to the continuation of the trial. Any early stopping for efficacy was to be based on the PP-EFF analysis set only.

The interim analyses were to follow standard group-sequential design using the O'Brien-Fleming boundary conditions. The nominal alpha to be spent for the final analysis was to be recalculated using the Lan-DeMets alpha spending function based on the actual numbers of events used for the interim analyses and the numbers of endpoints to be used for the final analysis.

In addition, a futility analysis was to be performed using the same data set (PP-EFF). The futility analysis would be based on the two-sided 95% CIs for the primary and key secondary efficacy endpoints based on the PP-EFF analysis set. The futility assessment was to be carried out for the 2 endpoints based on the upper bound of two-sided 95% CIs (UBCI) without a multiplicity adjustment:

1. UBCI for the primary efficacy endpoint (symptomatic COVID-19) < 50%
2. UBCI for the key secondary efficacy endpoint (moderate/severe COVID-19) < 50%

If both futility criteria were met, the independent DSMB was to make recommendations with regard to the discontinuation of the trial, with regard to continued vaccinations and/or blinded follow up of trial participants.

When the protocol was amended to implement the crossover design, the planned interim analyses were removed, and a single analysis was performed for the primary efficacy endpoint. No formal futility analysis was performed. It was determined that it would simply be no longer feasible or ethical to retain participants in the trial without providing active vaccine. Further, the available

efficacy data generated in the UK Phase 3 trial indicated the study would be adequately powered to conduct a final efficacy analysis with a minimum threshold of cases. This change effectively ended the placebo-controlled portion of the study to evaluate absolute vaccine efficacy at the time of crossover vaccination visits.

Thus, the current version of the protocol specifies that there are no formal interim analyses planned that require adjustment to Type I error. Analyses planned before end of study included a single analysis of primary and secondary efficacy endpoints. After Month 12, an analysis will be performed to examine durability effect of the vaccine on efficacy endpoints. The analysis at Month 12 will also report on safety follow-up through 1 year.

Supplemental Tables and Figures

Primary Efficacy End Point

The primary efficacy end point was the first episode of virologically confirmed (nasal swab RT-PCR-positive to SARS-CoV-2), symptomatic mild, moderate, or severe Covid-19 (see definitions in Table S1), with onset ≥7 days after completion of second study vaccination in serologically (to SARS-CoV-2 anti-Nucleoprotein, NP) and virologically (nasal swab RT-PCR) negative participants at baseline.

Table S2. Symptoms Suggestive of Covid-19

• Fever (body temperature >38.0°C, in the absence of other symptoms) or chills
• New onset or worsening of cough compared with baseline
• New onset or worsening of shortness of breath or difficulty breathing over baseline
• New onset of fatigue
• New onset of generalized muscle or body aches
• New onset of headache
• New loss of taste or smell
• Acute onset of sore throat
• Acute onset of congestion or runny nose
• New onset of nausea or vomiting
• New onset of diarrhea

Abbreviations: Covid-19 = coronavirus disease 2019.

Table S3. End Point Definitions of Covid-19 Severity

Covid-19 Severity	End Point Definitions
	First episode of RT-PCR-positive mild, moderate, or severe Covid-19:
Mild	**≥1 of the following:** • Fever (defined by subjective or objective measure, regardless of use of anti-pyretic medications) • New onset of cough • ≥2 additional Covid-19 symptoms: o New onset or worsening of shortness of breath or difficulty breathing compared to baseline. o New onset of fatigue. o New onset of generalized muscle or body aches. o New onset of headache. o New loss of taste or smell. o Acute onset of sore throat, congestion, or runny nose. o New onset of nausea, vomiting, or diarrhea.
Moderate*	**≥1 of the following:** • High fever (≥38.4°C) for ≥3 days (regardless of use of anti-pyretic medications, need not be contiguous days). • Any evidence of significant lower respiratory tract infection (LRTI): o Shortness of breath (or breathlessness or difficulty breathing) with or without exertion (greater than baseline). o Tachypnea: 24 to 29 breaths per minute at rest. o SpO_2: 94% to 95% on room air. o Abnormal chest X-ray or chest computerized tomography (CT) consistent with pneumonia or LRTI. • Adventitious sounds on lung auscultation (e.g., crackles/rales, wheeze, rhonchi, pleural rub, stridor).
Severe*	**≥1 of the following:** • Tachypnea: ≥30 breaths per minute at rest. • Resting heart rate ≥125 beats per minute. • SpO_2: ≤93% on room air or PaO_2/FiO_2 <300 mmHg. • High flow oxygen (O_2) therapy or non-invasive ventilation (NIV)/non-invasive positive pressure ventilation (NIPPV) (e.g., continuous positive airway pressure [CPAP] or bilevel positive airway pressure [BiPAP]). • Mechanical ventilation or extracorporeal membrane oxygenation (ECMO). • One or more major organ system dysfunction or failure to be defined by diagnostic testing/clinical syndrome/interventions, including any of the following: o Acute respiratory failure, including acute respiratory distress syndrome (ARDS). o Acute renal failure. o Acute hepatic failure. o Acute right or left heart failure. o Septic or cardiogenic shock (with shock defined as systolic blood pressure [SBP] <90 mm Hg OR diastolic blood pressure [DBP] <60 mm Hg). o Acute stroke (ischemic or hemorrhagic). o Acute thrombotic event: acute myocardial infarction (AMI), deep vein thrombosis (DVT), pulmonary embolism (PE). o Requirement for: vasopressors, systemic corticosteroids, or hemodialysis. • Admission to an intensive care unit (ICU). • Death.

Abbreviations: AMI = acute myocardial infarction; ARDS = acute respiratory distress syndrome; BiPAP = bi-level positive airway pressure; Covid-19 = coronavirus disease 2019; CPAP = continuous positive air pressure; CT = computerized tomography; DBP = diastolic blood pressure; DVT = deep vein thrombosis; ECMO = extracorporeal membrane oxygenation; FiO_2 = fraction of inspired oxygen; ICU = intensive care unit; LRTI = lower respiratory tract infection; NIV = non-invasive ventilation; NIPPV = non-invasive positive pressure ventilation; PaO_2 = partial pressure of oxygen in the alveolus; PE = pulmonary embolism; SBP = systolic blood pressure; SpO_2 = oxygen saturation.

* Participants with a single vital sign abnormality placing them in the moderate or severe categories must also meet the criteria for mild Covid-19.

Table S4. Demographics and Baseline Characteristics (Safety Analysis Set)

Parameter	NVX-CoV2373 N = 19,729	Placebo N = 9853	Total N = 29,582
Age (years)			
Mean (SD)	46.5 (15.05)	46.8 (14.95)	46.6 (15.02)
Median	47.0	47.0	47.0
Min, max	18 - 95	18 - 90	18 - 95
Age group, n (%)			
18 to ≤64 years	17,251 (87.4)	8616 (87.4)	25,867 (87.4)
≥65 years	2478 (12.6)	1237 (12.6)	3715 (12.6)
Sex, n (%)			
Male	10,409 (52.8)	5038 (51.1)	15,447 (52.2)
Female	9320 (47.2)	4815 (48.9)	14,135 (47.8)
Race, n (%)			
White	14,789 (75.0)	7384 (74.9)	22,173 (75.0)
Black or African American	2320 (11.8)	1167 (11.8)	3487 (11.8)
American Indian or Alaska Native	1309 (6.6)	662 (6.7)	1971 (6.7)
Asian	811 (4.1)	416 (4.2)	1227 (4.1)
Multiple	324 (1.6)	158 (1.6)	482 (1.6)
Native Hawaiian or Other Pacific Islander	56 (0.3)	12 (0.1)	68 (0.2)
Not reported	120 (0.6)	54 (0.5)	174 (0.6)
Ethnicity, n (%)			
Hispanic or Latino	4333 (21.9)	2154 (21.9)	6487 (21.9)
Not Hispanic or Latino	15,339 (77.7)	7676 (77.9)	23,015 (77.8)
Not reported	32 (0.2)	19 (0.2)	51 (0.2)
Unknown	25 (0.1)	4 (< 0.1)	29 (0.1)
Country, n (%)			
United States	18,553 (94.0)	9265 (94.0)	27,818 (94.0)
Mexico	1176 (6.0)	588 (6.0)	1764 (6.0)
Occupation, n (%)			
Currently working	13,442 (68.1)	6705 (68.1)	20,147 (68.1)
Working in close proximity to others	5019 (25.4)	2524 (25.6)	7543 (25.5)
Student attending school in person	1135 (5.8)	520 (5.3)	1655 (5.6)
In-person schooling/currently working/ working in close proximity to others, n (%)	14,965 (75.9)	7466 (75.8)	22,431 (75.8)
Days/week at workplace, n (%)			
0 days/week	3052 (15.5)	1609 (16.3)	4661 (15.8)
1 day/week	954 (4.8)	448 (4.5)	1402 (4.7)
2–4 days/week	3411 (17.3)	1729 (17.5)	5140 (17.4)
≥5 days/week	6009 (30.5)	2915 (29.6)	8924 (30.2)
PPE used by people at workplace	10,261 (52.0)	5078 (51.5)	15,339 (51.9)
Living situation, mean (SD)			
Number of people living with participant	2.0 (3.65)	1.9 (3.28)	2.0 (3.53)
Number of co-habitants under 18 years	0.6 (1.77)	0.6 (1.38)	0.6 (1.65)
Number of co-habitants 18 to 64 years	1.2 (2.71)	1.2 (3.00)	1.2 (2.81)

Parameter	NVX-CoV2373 N = 19,729	Placebo N = 9853	Total N = 29,582
Number of co-habitants ≥65 years	0.2 (0.46)	0.2 (0.45)	0.2 (0.46)
Lifestyle, n (%)			
History of smoking/vaping	6180 (31.3)	3090 (31.4)	9270 (31.3)
Currently smoking/vaping	3086 (15.6)	1528 (15.5)	4614 (15.6)
BMI category, n (%)			
Underweight (<18.0 kg/m^2)	142 (0.7)	60 (0.6)	202 (0.7)
Normal (18.0–24.9 kg/m^2)	5676 (28.8)	2804 (28.5)	8480 (28.7)
Overweight (25.0–29.9 kg/m^2)	6475 (32.8)	3243 (32.9)	9718 (32.9)
Obese (≥30.0 kg/m^2)	7339 (37.2)	3708 (37.6)	11,047 (37.3)
Comorbidities, n (%)			
Obesity (BMI ≥ kg/m^2)	7339 (37.2)	3708 (37.6)	11,047 (37.3)
Chronic lung disease	2745 (13.9)	1434 (14.6)	4179 (14.1)
Diabetes mellitus type 2	1517 (7.7)	813 (8.3)	2330 (7.9)
Cardiovascular disease	222 (1.1)	121 (1.2)	343 (1.2)
Chronic kidney disease	132 (0.7)	58 (0.6)	190 (0.6)
Overall high-risk adults,* n (%)			
Yes	18,805 (95.3)	9387 (95.3)	28,192 (95.3)
No	924 (4.7)	466 (4.7)	1390 (4.7)
High risk for developing severe Covid-19,† n (%)			
Yes	10,411 (52.8)	5248 (53.3)	15,659 (52.9)
No	9318 (47.2)	4605 (46.7)	13,923 (47.1)
HIV-positive, n (%)	148 (0.8)	61 (0.6)	209 (0.7)
Baseline serostatus, n (%)			
Seronegative and RT-PCR negative	18,489 (93.7)	9178 (93.1)	27,667 (93.5)
Seropositive or RT-PCR positive	1240 (6.3)	675 (6.9)	1915 (6.5)

Abbreviations: BMI = body mass index; max = maximum; min = minimum; NP = nucleocapsid; NVX-CoV2373 = 5 µg SARS-CoV-2 rS with 50 µg Matrix-M™ adjuvant; RT-PCR = reverse transcription-polymerase chain reaction; PPE = personal protective equipment; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine; SD = standard deviation.

* Overall high-risk adults were defined as 1) age ≥65 years with or without comorbidities and/or living or working conditions involving known frequent exposure to SARS-CoV-2 or to densely populated circumstances; 2) age <65 years with comorbidities and/or living or working conditions involving known frequent exposure to SARS-CoV-2 or to densely populated circumstances.

† High risk for development of severe Covid-19 include participants 1) age ≥65 years with or without comorbidities and/or 2) age <65 years with comorbidities.[7]

Table S5. Vaccine Efficacy Against RT-PCR-Confirmed Symptomatic Mild, Moderate, or Severe Covid-19 at Least 7 Days After Second Vaccination in Adult Participants Not Previously Exposed to SARS-CoV-2 (PP-EFF Analysis Set)

Parameter	NVX-CoV2373 N = 17,312	Placebo N = 8140
Participants with no occurrence of event,* n (%)	17,298 (99.9)	8077 (99.2)
Participants with occurrence of event,† n (%)	14 (0.1)	63 (0.8)
Severity of first occurrence, n (%)		
Mild	14 (0.1)	49 (0.6)
Moderate	0	10 (0.1)
Severe	0	4 (<0.1)
Median surveillance time‡ (days)	64.0	58.0
Log-linear model using modified Poisson regression§		
Mean disease incidence rate per year in 1000 people	3.26	34.01
95% CI	1.55, 6.89	20.70, 55.87
Relative risk	0.10	
95% CI	0.05, 0.17	
Vaccine efficacy (%)	90.40	
95% CI	82.88, 94.62	
P-value‖	<0.001	
Cox proportional hazard model (sensitivity analysis)ǀ		
Vaccine efficacy (%)	90.44	
95% CI	82.94, 94.64	
P-value#	<0.001	

Abbreviations: CI = confidence interval; Covid-19 = coronavirus disease 2019; NVX-CoV2373 = 5 µg SARS-CoV-2 rS with 50 µg Matrix-M™ adjuvant; RT-PCR = reverse transcriptase-polymerase chain reaction; PP-EFF = Per-Protocol Efficacy; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine; VE = vaccine efficacy.

* Includes participants with RT-PCR-confirmed infection who did not meet mild, moderate, or severe Covid-19 criteria.

† Event = first occurrence of RT-PCR-confirmed mild, moderate, or severe Covid-19 with onset of illness episode from at least 7 days after second vaccination within the surveillance period.

‡ Surveillance time was defined as the difference between the date at end of surveillance period (onset of first occurrence of event/ censoring) and date at start of surveillance period (7 days after the second injection) + 1.

§ Modified Poisson regression with logarithmic link function, treatment group, and age strata as fixed effects and robust error variance.[6]

‖ This P-value corresponded to a one-sided hypothesis test with significance level 0.025. If the VE P-value <0.025, then reject H0: VE ≤30%.

ǀ Cox-proportional hazard model with Efron's method for tie handling with vaccine group and age strata. Hazard ratio was used to estimate relative risk.

This P-value corresponded to a one-sided hypothesis test with significance level 0.025. If the VE P-value <0.025, then reject H0: VE ≤0%.

Table S6. Vaccine Efficacy Against RT-PCR-Confirmed Symptomatic Mild, Moderate, or Severe Covid-19 Due to a SARS-CoV-2 Variant Not Considered as a Variant of Concern or Variant of Interest at Least 7 Days After Second Vaccination in Adult Participants Not Previously Exposed to SARS-CoV-2 (PP-EFF Analysis Set)

Parameter	NVX-CoV2373 N = 17,312	Placebo N = 8140
Participants with no occurrence of event,* n (%)	17,312 (100.0)	8127 (99.8)
Participants with occurrence of event,† n (%)	0 (0.0)	13 (0.2)
Severity of first occurrence, n (%)		
Mild	0 (0.0)	10 (0.1)
Moderate	0 (0.0)	2 (<0.1)
Severe	0 (0.0)	1 (<0.1)
Median surveillance time‡ (days)	64.0	58.0
Exact conditional binomial method substituted for log-linear model using modified Poisson regression§		
Mean disease incidence rate per year in 1000 people	0.00	10.18
95% CI	<0.01, 1.25	5.42, 17.41
Relative risk	0.00	
95% CI	<0.01, 0.14	
Vaccine efficacy (%)	100.00	
95% CI	85.84, 100.00	
P-value‖	<0.001	

Abbreviations: CDC = Centers for Disease Control and Prevention; CI = confidence interval; Covid-19 = coronavirus disease 2019; NVX-CoV2373 = 5 µg SARS-CoV-2 rS with 50 µg Matrix-M™ adjuvant; RT-PCR = reverse transcriptase-polymerase chain reaction; PP-EFF = Per-Protocol Efficacy; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine; SIG = SARS-CoV-2 Interagency Group; VE = vaccine efficacy; VOC = variant of concern; VOI = variant of interest.

* Includes participants with RT-PCR-confirmed infection who did not meet mild, moderate, or severe Covid-19 criteria and not considered a VOC or VOI.

† Event = first occurrence of RT-PCR-confirmed mild, moderate, or severe Covid-19 due to a SARS-CoV-2 variant not considered as a VOC or VOI with onset of illness episode from at least 7 days after second vaccination within the surveillance period.

‡ Surveillance time was defined as the difference between the date at end of surveillance period (onset of first occurrence of event/censoring) and date at start of surveillance period (7 days after the second injection) + 1.

§ In the event when there were zero cases in either group or the total number of cases in both treatment groups combined <5, VE and 95% CI were estimated with 1 – ratio of incidence rates using the exact method conditional on the total number of cases.

‖ This P-value corresponded to a one-sided hypothesis test with significance level 0.025. If the VE P-value <0.025, then reject H_0: VE ≤30%.

Note: VOC/VOI were established by SIG and CDC for SARS-CoV-2 Variant Classifications and Definitions.[3]

Table S7. Vaccine Efficacy Against RT-PCR-Confirmed Symptomatic Moderate or Severe Covid-19 at Least 7 Days After Second Vaccination in Adult Participants Not Previously Exposed to SARS-CoV-2 (PP-EFF Analysis Set)

Parameter	NVX-CoV2373 N = 17,312	Placebo N = 8140
Participants with no occurrence of event,* n (%)	17,312 (100.0)	8126 (99.8)
Participants with occurrence of event,† n (%)	0 (0.0)	14 (0.2)
Severity of first occurrence, n (%)		
Moderate	0 (0.0)	10 (0.1)
Severe	0 (0.0)	4 (<0.1)
Median surveillance time‡ (days)	64.0	58.0
Exact conditional binomial method substituted for log-linear model using modified Poisson regression§		
Mean disease incidence rate per year in 1000 people	0.00	10.96
95% CI	0.00, 1.25	5.99, 18.40
Relative risk	0.00	
95% CI	0.00, 0.13	
Vaccine efficacy (%)	100.00	
95% CI	86.99, 100.00	
P-value‖	<0.001	

Abbreviations: CI = confidence interval; COVID-19 = coronavirus disease 2019; NVX-CoV2373 = 5 µg SARS-CoV-2 rS with 50 µg Matrix-M™ adjuvant; RT-PCR = reverse transcriptase-polymerase chain reaction; PP-EFF = Per-Protocol Efficacy; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine; VE = vaccine efficacy.

* Includes participants with RT-PCR-confirmed infection who did not meet moderate or severe Covid-19 criteria.

† Event = first occurrence of RT-PCR-confirmed moderate or severe Covid-19 with onset of illness episode from at least 7 days after second vaccination within the surveillance period.

‡ Surveillance time was defined as the difference between the date at end of surveillance period (onset of first occurrence of event/censoring) and date at start of surveillance period (7 days after the second injection) + 1.

§ In the event when there were zero cases in either group or the total number of cases in both treatment groups combined <5, VE and 95% CI were estimated with 1 – ratio of incidence rates using the exact method conditional on the total number of cases. NE = not estimable in the event the test for exact binomial proportion could not be conducted.

‖ This P-value corresponds to a one-sided hypothesis test with significance level 0.025. If the VE P-value <0.025, then reject H_0: VE ≤0%.

Table S8. Vaccine Efficacy Against RT-PCR-Confirmed Symptomatic Mild, Moderate or Severe Covid-19 Due to a SARS-CoV-2 Variant Considered as a Variant of Concern or Variant of Interest at Least 7 Days After Second Vaccination in Adult Participants Not Previously Exposed to SARS-CoV-2 (PP-EFF Analysis Set)

Parameter	NVX-CoV2373 N = 17,312	Placebo N = 8140
Participants with no occurrence of event,* n (%)	17,305 (100.0)	8099 (99.5)
Participants with occurrence of event,† n (%)	7 (<0.1)	41 (0.5)
Severity of first occurrence, n (%)		
Mild	7 (<0.1)	31 (0.4)
Moderate	0 (0.0)	8 (0.1)
Severe	0 (0.0)	2 (<0.1)
Median surveillance time‡ (days)	64.0	58.0
Log-linear model using modified Poisson regression§		
Mean disease incidence rate per year in 1000 people	1.47	19.93
95% CI	0.50, 4.30	9.95, 39.94
Relative risk	0.07	
95% CI	0.03, 0.16	
Vaccine efficacy (%)	92.62	
95% CI	83.56, 96.69	
P-value‖	<0.001	

Abbreviations: CI = confidence interval; Covid-19 = coronavirus disease 2019; NVX-CoV2373 = 5 µg SARS-CoV-2 rS with 50 µg Matrix-M™ adjuvant; RT-PCR = reverse transcriptase-polymerase chain reaction; PP-EFF = Per-Protocol Efficacy; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine; VE = vaccine efficacy; VOC = variant of concern; VOI = variant of interest.

* Includes participants with RT-PCR-confirmed infection who did not meet mild, moderate, or severe Covid-19 criteria and not considered a VOC or VOI.

† Event = first occurrence of RT-PCR-confirmed mild, moderate, or severe Covid-19 due to a VOC or VOI with onset of illness episode from at least 7 days after second vaccination within the surveillance period.

‡ Surveillance time was defined as the difference between the date at end of surveillance period (onset of first occurrence of event/censoring) and date at start of surveillance period (7 days after the second injection) + 1.

§ Modified Poisson regression with logarithmic link function, treatment group, and age strata as fixed effects and robust error variance.[6]

‖ This P-value corresponded to a one-sided hypothesis test with significance level 0.025. If the VE P-value <0.025, then reject H_0: VE ≤0%.

Note: VOC/VOI were established by SIG and CDC for SARS-CoV-2 Variant Classifications and Definitions.[3]

Figure S1. SARS-CoV-2 Clade/Variant Identified in Per-Protocol Efficacy Covid-19 End Point Cases by Disease Severity

	NVX-CoV2373 (n=17,312)		Placebo (n=8,140)	
Total	**14**		**63**	
	Variant	**N (%)**	**Variant**	**N (%)**
Mild Disease	*Alpha (B.1.1.7)* *Beta (B.1.351)* *Iota (B.1.526)* *No sequence available*	*4* *1* *2* *7*	*Alpha (B.1.1.7)* *Beta (B.1.351)* *Gamma (P.1)* *Epsilon (B.1.429)* *Iota (B.1.526)* *Kappa (B.1.617.1)* *Zeta (P.2)* *B.1* *B.1.1* *B.1.1.316* *B.1.1.519* *B.1.2* *B.1.243* *B.1.311* *B.1.596* *No sequence available*	*20* *1* *2* *1* *5* *1* *1* *1* *1* *1* *1* *1* *2* *2* *1* *8*
Moderate Disease	n/a	0	*Alpha (B.1.1.7)* *Epsilon (B.1.429)* *B.1.2*	*6* *2* *2*
Severe Disease	n/a	0	*Alpha (B.1.1.7)* *Iota (B.1.526)* *B.1.2* *No sequence available*	*1* *1* *1* *1*

Abbreviations: Covid-19 = coronavirus disease 2019; NVX-CoV2373 = 5 µg SARS-CoV-2 rS with 50 µg Matrix-M™ adjuvant; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2, SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine.

Red: VOC, variant of concern, Orange: VOI, variant of interest, Green: not a VOC/VOI, as per CDC Classification.[3]

Table S9. Overall Summary of Treatment-Emergent Adverse Events Reported From After Start of First Vaccination to Blinded Crossover or Early Withdrawal (Safety Analysis Set)

TEAE Category	NVX-CoV2373 N = 19,729		Placebo N = 9853	
	n (%)	E	n (%)	E
Any TEAE	3216 (16.3)	5647	1456 (14.8)	2491
Any severe TEAE*	244 (1.2)	353	106 (1.1)	162
Any treatment-related TEAE *	798 (4.0)	1422	239 (2.4)	365
Any severe treatment-related TEAE*	55 (0.3)	77	10 (0.1)	18
Any MAAE	1387 (7.0)	1995	651 (6.6)	938
Any treatment-related MAAE*	88 (0.4)	125	30 (0.3)	36
Any serious treatment-related MAAE*	5 (< 0.1)	8	0	0
Any serious TEAE	169 (0.9)	228	94 (1.0)	128
Any TEAE leading to vaccination discontinuation	57 (0.3)	102	16 (0.2)	26
Any treatment-related TEAE leading to vaccination discontinuation*	10 (0.1)	17	3 (<0.1)	4
Any TEAE leading to study discontinuation	60 (0.3)	65	13 (0.1)	14
Any treatment-related TEAE leading to study discontinuation*	14 (0.1)	17	2 (<0.1)	2
Any AESI: PIMMC	16 (0.1)	21	3 (<0.1)	4
Any treatment-related AESI: PIMMC*	10 (0.1)	15	1 (<0.1)	1
Any AESI: relevant to Covid-19	4 (<0.1)	6	4 (<0.1)	7
Any treatment-related AESI: relevant to Covid-19*	0	0	0	0

Abbreviations: AESI = adverse event of special interest; Covid-19 = coronavirus disease 2019; E = number of events at each level of summarization; MAAE = medically attended adverse event; NVX-CoV2373 = 5 µg SARS-CoV-2 rS with 50 µg Matrix-M™ adjuvant; PIMMC = potential immune-mediated medical conditions; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine; TEAE = treatment-emergent adverse event.

* Relationship and severity were based on the data reported by site, i.e., missing information was not imputed.

Table S10. Summary of Solicited Local Adverse Events Within 7 Days After Dose 1 and Dose 2 in All Participants (Safety Analysis Set)

Solicited Local Adverse Events	All Participants	
	NVX-CoV2373 N = 19,729/19,104 (%)	Placebo N = 9853/9422 (%)
Any local adverse event, N1/N2	**18,072/17,139**	**8904/8278**
Dose 1 (Grade ≥1)	10,475 (57.96)	1881 (21.13)
Grade 3	197 (1.09)	22 (0.25)
Grade 4	1 (< 0.01)	1 (0.01)
Dose 2 (Grade ≥1)	13,525 (78.91)	1797 (21.71)
Grade 3	1140 (6.65)	25 (0.30)
Grade 4	7 (0.04)	1 (0.01)
Any pain, N1/N2	**18,072/17,139**	**8904/8278**
Dose 1 (Grade ≥1)	6211 (34.37)	986 (11.07)
Grade 3	55 (0.30)	3 (0.03)
Grade 4	0	0
Dose 2 (Grade ≥1)	10,227 (59.67)	1141 (13.78)
Grade 3	297 (1.73)	7 (0.08)
Grade 4	5 (0.03)	1 (0.01)
Any tenderness, N1/N2	**18,072/17,139**	**8904/8278**
Dose 1 (Grade ≥1)	9450 (52.29)	1494 (16.78)
Grade 3	156 (0.86)	18 (0.20)
Grade 4	1 (<0.01)	1 (0.01)
Dose 2 (Grade ≥1)	12,584 (73.42)	1312 (15.85)
Grade 3	834 (4.87)	18 (0.22)
Grade 4	3 (0.02)	0
Any erythema, N1/N2	**18,072/17,139**	**8904/8278**
Dose 1 (Grade ≥1)	164 (0.91)	27 (0.30)
Grade 3	3 (0.02)	0
Grade 4	0	0
Dose 2 (Grade ≥1)	1138 (6.64)	29 (035)
Grade 3	143 (0.83)	2 (0.02)
Grade 4	0	0
Any swelling, N1/N2	**18,072/17,139**	**8904/8278**
Dose 1 (Grade ≥1)	154 (0.85)	24 (0.27)
Grade 3	7 (0.04)	3 (0.03)
Grade 4	0	0
Dose 2 (Grade ≥1)	1056 (6.16)	25 (0.30)
Grade 3	91 (0.53)	2 (0.02)
Grade 4	0	0

Abbreviations: FDA = US Food and Drug Administration; N = number of participants in the Safety Analysis Set following Dose 1/Dose 2; N1 = number of participants in the Safety Analysis Set who received the first dose and completed at least 1 day of the reactogenicity diary; N2 = number of participants in the Safety Analysis Set who received the second dose and completed at least 1 day of the reactogenicity diary; NVX-CoV2373 = 5 µg SARS-CoV-2 rS with 50 µg Matrix-M™ adjuvant; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine.

Note: Data are presented as number (%) of participants experiencing a solicited event. Percentages were based on n/N1 × 100 and n/N2 × 100. At each level of participant summarization, a participant was counted once if they indicated the event.

Note: Grading of solicited adverse events was based on FDA Toxicity Grading Scale for Clinical Abnormalities.[8]

Table S11. Duration (Days) of Solicited Local Adverse Events Within 7 Days After Dose 1 and Dose 2 in All Participants (Safety Analysis Set)

Solicited Local Adverse Events	NVX-CoV2373 N = 19,729/19,104	Placebo N = 9853/9422
Pain (# of days ≥ grade 1), N1/N2	**18,072/17,139**	**8904/8278**
Dose 1, n	6210	986
Median	1.0	1.0
Minimum - maximum	1 - 7	1 - 7
Dose 2, n	10226	1141
Median	2.0	1.0
Minimum - maximum	1 - 7	1 - 7
Tenderness (# of days ≥ grade 1), N1/N2	**18,072/17,139**	**8904/8278**
Dose 1, n	9450	1494
Median	2.0	1.0
Minimum - maximum	1 - 7	1 - 7
Dose 2, n	12584	1312
Median	2.0	1.0
Minimum - maximum	1 - 7	1 - 7
Erythema (# of days ≥ grade 1), N1/N2	**18,072/17,139**	**8904/8278**
Dose 1, n	164	27
Median	1.0	1.0
Minimum - maximum	1 - 7	1 - 5
Dose 2, n	1138	29
Median	2.0	1.0
Minimum - maximum	1 - 7	1 - 6
Swelling (# of days ≥ grade 1), N1/N2	**18,072/17,139**	**8904/8278**
Dose 1, n	154	24
Median	1.0	1.0
Minimum - maximum	1 - 7	1 - 5
Dose 2, n	1056	25
Median	2.0	1.0
Minimum - maximum	1 - 7	1 - 5

Abbreviations: n = number of participants who reported the solicited event; N = number of participants in the Safety Analysis Set following Dose 1/Dose 2; N1 = number of participants in the Safety Analysis Set who received the first dose and completed at least 1 day of the reactogenicity diary; N2 = number of participants in the Safety Analysis Set who received the second dose and completed at least 1 day of the reactogenicity diary; NVX-CoV2373 = 5 μg SARS-CoV-2 rS with 50 μg Matrix-M™ adjuvant; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine.

Note: Duration is calculated as the number of days the solicited event was greater than grade 0. n = number of subjects who reported the event.

Table S12. Summary of Solicited Systemic Adverse Events Within 7 Days After Dose 1 and Dose 2 by Age Group (Safety Analysis Set)

Solicited Systemic Adverse Events	All Participants	
	NVX-CoV2373 N = 19,729/19,104 (%)	Placebo N = 9853/9422 (%)
Any solicited systemic TEAE, N1/N2	**18,072/17,139**	**8904/8278**
Dose 1 (Grade ≥1)	8614 (47.66)	3562 (40.00)
Grade 3	422 (2.34)	183 (2.06)
Grade 4	17 (0.09)	5 (0.06)
Dose 2 (Grade ≥1)	11,906 (69.47)	2969 (35.87)
Grade 3	2056 (12.00)	165 (1.99)
Grade 4	21 (0.12)	5 (0.06)
Headache, N1/N2	**18,072/17,139**	**8904/8278**
Dose 1 (Grade ≥1)	4505 (24.93)	2028 (22.78)
Grade 3	146 (0.81)	62 (0.70)
Grade 4	5 (0.03)	1 (0.01)
Dose 2 (Grade ≥1)	7618 (44.45)	1625 (19.63)
Grade 3	512 (2.99)	36 (0.43)
Grade 4	6 (0.04)	2 (0.02)
Fatigue, N1/N2	**18,072/17,139**	**8904/8278**
Dose 1 (Grade ≥1)	4632 (25.63)	1993 (22.38)
Grade 3	224 (1.24)	100 (1.12)
Grade 4	3 (0.02)	1 (0.01)
Dose 2 (Grade ≥1)	8486 (49.51)	1811 (21.88)
Grade 3	1419 (8.28)	108 (1.30)
Grade 4	4 (0.02)	3 (0.04)
Malaise, N1/N2	**18,072/17,139**	**8904/8278**
Dose 1 (Grade ≥1)	2660 (14.72)	1037 (11.65)
Grade 3	137 (0.76)	53 (0.60)
Grade 4	7 (0.04)	2 (0.02)
Dose 2 (Grade ≥1)	6674 (38.94)	1018 (12.30)
Grade 3	1073 (6.26)	57 (0.69)
Grade 4	9 (0.05)	2 (0.02)
Muscle pain, N1/N2	**18,072/17,139**	**8904/8278**
Dose 1 (Grade ≥1)	4102 (22.70)	1188 (13.34)
Grade 3	81 (0.45)	35 (0.39)
Grade 4	2 (0.01)	2 (0.02)
Dose 2 (Grade ≥1)	8240 (48.08)	1001 (12.09)
Grade 3	841 (4.91)	29 (0.35)
Grade 4	5 (0.03)	4 (0.05)
Joint pain, N1/N2	**18,072/17,139**	**8904/8278**
Dose 1 (Grade ≥1)	1388 (7.68)	590 (6.63)

Solicited Systemic Adverse Events	All Participants	
	NVX-CoV2373 N = 19,729/19,104 (%)	**Placebo N = 9853/9422 (%)**
Grade 3	51 (0.28)	29 (0.33)
Grade 4	1 (< 0.01)	0
Dose 2 (Grade ≥1)	3809 (22.22)	567 (6.85)
Grade 3	411 (2.40)	24 (0.29)
Grade 4	6 (0.04)	2 (0.02)
Fever, N1/N2	**18,072/17,139**	**8904/8278**
Dose 1 (Grade ≥1)	66 (0.37)	33 (0.37)
Grade 3	8 (0.04)	6 (0.07)
Grade 4	6 (0.03)	1 (0.01)
Dose 2 (Grade ≥1)	973 (5.68)	23 (0.28)
Grade 3	62 (0.36)	3 (0.04)
Grade 4	2 (0.01)	0
Nausea/Vomiting, N1/N2	**18,072/17,139**	**8904/8278**
Dose 1 (Grade ≥1)	1152 (6.37)	488 (5.48)
Grade 3	17 (0.09)	7 (0.08)
Grade 4	4 (0.02)	3 (0.03)
Dose 2 (Grade ≥1)	1929 (11.26)	450 (5.44)
Grade 3	29 (0.17)	7 (0.08)
Grade 4	7 (0.04)	2 (0.02)

Abbreviations: FDA = US Food and Drug Administration; N = number of participants in the Safety Analysis Set following Dose 1/Dose 2; N1 = number of participants in the Safety Analysis Set who received the first dose and completed at least 1 day of the reactogenicity diary; N2 = number of participants in the Safety Analysis Set who received the second dose and completed at least 1 day of the reactogenicity diary; NVX-CoV2373 = 5 µg SARS-CoV-2 rS with 50 µg Matrix-M™ adjuvant; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine.

Note: Data are presented as number (%) of participants experiencing a solicited event. Percentages were based on n/N1 × 100 and n/N2 × 100. At each level of participant summarization, a participant was counted once if they indicated the event occurred and provided a severity during the reactogenicity period. The highest severity experienced during the reactogenicity period is summarized in this table.

Note: Grading of solicited adverse events was based on FDA Toxicity Grading Scale for Clinical Abnormalities.[8]

Table S13. Duration (Days) of Solicited Systemic Adverse Events Within 7 Days After Dose 1 and Dose 2 in All Participants (Safety Analysis Set)

Solicited Systemic Adverse Events	NVX-CoV2373 N = 19,729/19,104	Placebo N = 9853/9422
Headache (# of days ≥ grade 1), N1/N2	**18,072/17,139**	**8904/8278**
Dose 1, n	4505	2028
Median	1.0	1.0
Minimum - maximum	1 - 7	1 - 7
Dose 2, n	7618	1625
Median	1.0	1.0
Minimum - maximum	1 - 7	1 - 7
Fatigue (# of days ≥ grade 1), N1/N2	**18,072/17,139**	**8904/8278**
Dose 1, n	4632	1993
Median	1.0	1.0
Minimum - maximum	1 - 7	1 - 7
Dose 2, n	8486	1811
Median	1.0	1.0
Minimum - maximum	1 - 7	1 - 7
Malaise (# of days ≥ grade 1), N1/N2	**18,072/17,139**	**8904/8278**
Dose 1, n	2660	1037
Median	1.0	1.0
Minimum - maximum	1 - 7	1 - 7
Dose 2, n	6674	1018
Median	1.0	1.0
Minimum - maximum	1 - 7	1 - 7
Muscle pain (# of days ≥ grade 1), N1/N2	**18,072/17,139**	**8904/8278**
Dose 1, n	4102	1188
Median	1.0	1.0
Minimum - maximum	1 - 7	1 - 7
Dose 2, n	8240	1000
Median	1.0	1.0
Minimum - maximum	1 - 7	1 - 7
Joint pain (# of days ≥ grade 1), N1/N2	**18,072/17,139**	**8904/8278**
Dose 1, n	1388	590
Median	1.0	1.0
Minimum - maximum	1 - 7	1 - 7
Dose 2, n	3809	567
Median	1.0	1.0
Minimum - maximum	1 - 7	1 - 7
Fever (# of days ≥ grade 1), N1/N2	**18,072/17,139**	**8904/8278**
Dose 1, n	66	33
Median	1.0	1.0
Minimum - maximum	1 - 5	1 - 2
Dose 2, n	973	23
Median	1.0	1.0

Solicited Systemic Adverse Events	NVX-CoV2373 N = 19,729/19,104	Placebo N = 9853/9422
Minimum - maximum	1 - 6	1 - 4
Nausea/Vomiting (# of days ≥ grade 1), N1/N2	**18,072/17,139**	**8904/8278**
Dose 1, n	1152	488
Median	1.0	1.0
Minimum - maximum	1 - 7	1 - 6
Dose 2, n	1929	450
Median	1.0	1.0
Minimum - maximum	1 - 7	1 - 7

Abbreviations: n = number of participants who reported the solicited event; N = number of participants in the Safety Analysis Set following Dose 1/Dose 2; N1 = number of participants in the Safety Analysis Set who received the first dose and completed at least 1 day of the reactogenicity diary; N2 = number of participants in the Safety Analysis Set who received the second dose and completed at least 1 day of the reactogenicity diary; NVX-CoV2373 = 5 μg SARS-CoV-2 rS with 50 μg Matrix-M™ adjuvant; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine.

Note: Duration is calculated as the number of days the solicited event was greater than grade 0. n=number of subjects who reported the event.

Table S14. Summary of Unsolicited Adverse Events by System Organ Class and Preferred Term Reported From After Start of First Vaccination Through 28 Days After Second Vaccination (e.g., Day 49) for Events With an Incidence Rate ≥1 Event per 100 Person-Years by Age Strata (Safety Analysis Set)

System Organ Class/Preferred Term (MedDRA, Version 23.1)	Participants ≥18 Years				Participants 18 to ≤64 Years				Participants ≥65 Years			
	NVX-CoV2373 N = 19,729		Placebo N = 9853		NVX-CoV2373 N = 17,251		Placebo N = 8616		NVX-CoV2373 N = 2478		Placebo N = 1237	
	E	IR	E	IR	E	IR	E	IR	E	IR	E	IR
Number of participants experiencing an event	**4299**	**156.37**	**1794**	**131.98**	**3781**	**156.87**	**1590**	**133.15**	**518**	**152.84**	**204**	**123.56**
General disorders and administration site conditions	**925**	**33.65**	**228**	**16.77**	**831**	**34.48**	**203**	**17.00**	**94**	**27.73**	**25**	**15.14**
Fatigue	196	7.13	69	5.08	173	7.18	63	5.28	23	6.79	6	3.63
Injection site pain	160	5.82	38	2.80	139	5.77	31	2.60	21	6.20	7	4.24
Pyrexia	116	4.22	23	1.69	109	4.52	22	1.84	7	2.07	1	0.61
Pain	68	2.47	21	1.54	61	2.53	21	1.76	7	2.07	0	0
Chills	65	2.36	6	0.44	61	2.53	6	0.50	4	1.18	0	0
Malaise	48	1.75	14	1.03	44	1.83	12	1.00	4	1.18	2	1.21
Injection site pruritus	44	1.60	2	0.15	39	1.62	2	0.17	5	1.48	0	0
Injection site erythema	29	1.05	4	0.29	28	1.16	4	0.33	1	0.30	0	0
Edema peripheral	15	0.55	4	0.29	10	0.41	2	0.17	5	1.48	2	1.21
Nervous system disorders	**514**	**18.70**	**246**	**18.10**	**461**	**19.13**	**223**	**18.67**	**53**	**15.64**	**23**	**13.93**
Headache	293	10.66	130	9.56	271	11.24	118	9.88	22	6.49	12	7.27
Dizziness	45	1.64	23	1.69	37	1.54	20	1.67	8	2.36	3	1.82
Tension headache	27	0.98	15	1.10	21	0.87	13	1.09	6	1.77	2	1.21
Infections and infestations	**507**	**18.44**	**284**	**20.89**	**445**	**18.46**	**250**	**20.94**	**62**	**18.29**	**34**	**20.59**
Upper respiratory tract infection	63	2.29	31	2.28	55	2.28	27	2.26	8	2.36	4	2.42
Urinary tract infection	52	1.89	19	1.40	43	1.78	14	1.17	9	2.66	5	3.03
Covid-19	49	1.78	38	2.80	42	1.74	36	3.01	7	2.07	2	1.21
Viral infection	31	1.13	17	1.25	27	1.12	16	1.34	4	1.18	1	0.61
Sinusitis	29	1.05	18	1.32	23	0.95	17	1.42	6	1.77	1	0.61
Cellulitis	15	0.55	8	0.59	11	0.46	5	0.42	4	1.18	3	1.82
Tooth infection	4	0.15	15	1.10	4	0.17	13	1.09	0	0	2	1.21
Respiratory, thoracic, and mediastinal disorders	**415**	**15.09**	**210**	**15.45**	**364**	**15.10**	**189**	**15.83**	**51**	**15.05**	**21**	**12.72**

System Organ Class/Preferred Term (MedDRA, Version 23.1)	Participants ≥18 Years				Participants 18 to ≤64 Years				Participants ≥65 Years			
	NVX-CoV2373 N = 19,729		Placebo N = 9853		NVX-CoV2373 N = 17,251		Placebo N = 8616		NVX-CoV2373 N = 2478		Placebo N = 1237	
	E	IR	E	IR	E	IR	E	IR	E	IR	E	IR
Nasal congestion	111	4.04	67	4.93	97	4.02	62	5.19	14	4.13	5	3.03
Cough	78	2.84	41	3.02	68	2.82	38	3.18	10	2.95	3	1.82
Rhinorrhea	55	2.00	20	1.47	45	1.87	17	1.42	10	2.95	3	1.82
Oropharyngeal pain	48	1.75	27	1.99	42	1.74	27	2.26	6	1.77	0	0
Dyspnea	32	1.16	18	1.32	31	1.29	14	1.17	1	0.30	4	2.42
Musculoskeletal and connective tissue disorders	**378**	**13.75**	**161**	**11.84**	**326**	**13.53**	**132**	**11.05**	**52**	**15.34**	**29**	**17.56**
Myalgia	109	3.96	30	2.21	93	3.86	24	2.01	16	4.72	6	3.63
Arthralgia	64	2.33	36	2.65	56	2.32	32	2.68	8	2.36	4	2.42
Pain in extremity	51	1.86	17	1.25	47	1.95	15	1.26	4	1.18	2	1.21
Back pain	38	1.38	21	1.54	33	1.37	17	1.42	5	1.48	4	2.42
Osteoarthritis	11	0.40	5	0.37	8	0.33	2	0.17	3	0.89	3	1.82
Gastrointestinal disorders	**376**	**13.68**	**189**	**13.90**	**335**	**13.90**	**174**	**14.57**	**41**	**12.10**	**15**	**9.09**
Diarrhea	89	3.24	60	4.41	73	3.03	57	4.77	16	4.72	3	1.82
Nausea	86	3.13	39	2.87	80	3.32	34	2.85	6	1.77	5	3.03
Vomiting	35	1.27	12	0.88	34	1.41	11	0.92	1	0.30	1	0.61
Gastroesophageal reflux disease	15	0.55	6	0.44	14	0.58	4	0.33	1	0.30	2	1.21
Skin and subcutaneous tissue disorders	**218**	**7.93**	**71**	**5.22**	**197**	**8.17**	**67**	**5.61**	**21**	**6.20**	**4**	**2.42**
Rash	61	2.22	22	1.62	55	2.28	21	1.76	6	1.77	1	0.61
Injury, poisoning, and procedural complications	**205**	**7.46**	**102**	**7.50**	**173**	**7.18**	**87**	**7.29**	**32**	**9.44**	**15**	**9.09**
Ligament sprain	11	0.40	8	0.59	9	0.37	6	0.50	2	0.59	2	1.21
Fall	10	0.36	7	0.51	6	0.25	4	0.33	4	1.18	3	1.82
Psychiatric disorders	**109**	**3.96**	**48**	**3.53**	**103**	**4.27**	**47**	**3.94**	**6**	**1.77**	**1**	**0.61**
Anxiety	32	1.16	14	1.03	31	1.29	13	1.09	1	0.30	1	0.61
Vascular disorders	**108**	**3.93**	**50**	**3.68**	**82**	**3.40**	**43**	**3.60**	**26**	**7.67**	**7**	**4.24**
Hypertension	71	2.58	40	2.94	54	2.24	36	3.01	17	5.02	4	2.42
Metabolism and nutrition disorders	**79**	**2.87**	**47**	**3.46**	**62**	**2.57**	**44**	**3.68**	**17**	**5.02**	**3**	**1.82**
Blood and lymphatic disorders	**78**	**2.84**	**22**	**1.62**	**76**	**3.15**	**21**	**1.76**	**2**	**0.59**	**1**	**0.61**
Lymphadenopathy	53	1.93	13	0.96	52	2.16	12	1.00	1	0.30	1	0.61
Investigations	**67**	**2.44**	**28**	**2.06**	**54**	**2.24**	**23**	**1.93**	**13**	**3.84**	**5**	**3.03**

System Organ Class/Preferred Term (MedDRA, Version 23.1)	Participants ≥18 Years				Participants 18 to ≤64 Years				Participants ≥65 Years			
	NVX-CoV2373 N = 19,729		Placebo N = 9853		NVX-CoV2373 N = 17,251		Placebo N = 8616		NVX-CoV2373 N = 2478		Placebo N = 1237	
	E	IR	E	IR	E	IR	E	IR	E	IR	E	IR
Blood pressure increased	15	0.55	5	0.37	12	0.50	3	0.25	3	0.89	2	1.21
SARS-CoV-2 test positive	12	0.44	12	0.88	10	0.41	10	0.84	2	0.59	2	1.21
Eye disorders	**62**	**2.26**	**13**	**0.96**	**54**	**2.24**	**10**	**0.84**	**8**	**2.36**	**3**	**1.82**
Reproductive system and breast disorders	**55**	**2.00**	**17**	**1.25**	**51**	**2.12**	**15**	**1.26**	**4**	**1.18**	**2**	**1.21**
Cardiac disorders	**45**	**1.64**	**21**	**1.54**	**34**	**1.41**	**14**	**1.17**	**11**	**3.25**	**7**	**4.24**
Ear and labyrinth disorders	**44**	**1.60**	**16**	**1.18**	**39**	**1.62**	**13**	**1.09**	**5**	**1.48**	**3**	**1.82**
Immune system disorders	**29**	**1.05**	**7**	**0.51**	**27**	**1.12**	**7**	**0.59**	**2**	**0.59**	**0**	**0**
Neoplasms benign, malignant and unspecified (including cysts and polyps)	**26**	**0.95**	**7**	**0.51**	**19**	**0.79**	**4**	**0.33**	**7**	**2.07**	**3**	**1.82**
Renal and urinary disorders	**26**	**0.95**	**10**	**0.74**	**17**	**0.71**	**9**	**0.75**	**9**	**2.66**	**1**	**0.61**

Abbreviations: E = number of AEs reported; IR = incidence rate is defined as number of events per 100 person-years = e/100 PY; MedDRA = Medical Dictionary for Regulatory Activities; NVX-CoV2373 = 5 µg SARS-CoV-2 rS with 50 µg Matrix-M™ adjuvant; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine.

Note: Events and IRs at the system organ class level represent all events.

Table S15. Summary of Unsolicited Serious Adverse Events by System Organ Class and Preferred Term From Start of First Vaccination to Blinded Crossover or Early Termination by Age Strata (Safety Analysis Set)

System Organ Class/ Preferred Term (MedDRA, Version 23.1)	Participants ≥18 Years				Participants 18 to ≤64 Years				Participants ≥65 Years			
	NVX-CoV2373 N = 19,729		Placebo N = 9853		NVX-CoV2373 N = 17,251		Placebo N = 8616		NVX-CoV2373 N = 2478		Placebo N = 1237	
	E	IR	E	IR	E	IR	E	IR	E	IR	E	IR
Number of participants experiencing an event	**228**	**4.32**	**128**	**4.89**	**169**	**3.68**	**103**	**4.52**	**59**	**8.48**	**25**	**7.41**
Infections and infestations	**33**	**0.62**	**35**	**1.34**	**26**	**0.57**	**28**	**1.23**	**7**	**1.01**	**7**	**2.08**
Appendicitis	5	0.09	4	0.15	4	0.09	4	0.18	1	0.14	0	0
Covid-19	5	0.09	9	0.34	3	0.07	8	0.35	2	0.29	1	0.30
Pneumonia	4	0.08	2	0.08	2	0.04	1	0.04	2	0.29	1	0.30
Cellulitis	2	0.04	2	0.08	1	0.02	1	0.04	1	0.14	1	0.30
Sepsis	2	0.04	2	0.08	1	0.02	1	0.04	1	0.14	1	0.30
Abscess limb	1	0.02	1	0.04	1	0.02	1	0.04	0	0	0	0
Appendicitis perforated	1	0.02	1	0.04	1	0.02	1	0.04	0	0	0	0
Arthritis bacterial	1	0.02	1	0.04	1	0.02	0	0	0	0	1	0.30
Empyema	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Localized infection	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Mastitis	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Necrotizing soft tissue infection	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Osteomyelitis	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Perineal abscess	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Post-procedural infection	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Pyelonephritis	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Septic shock	1	0.02	1	0.04	1	0.02	1	0.04	0	0	0	0
Subcutaneous abscess	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Urosepsis	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Abdominal wall abscess	0	0	1	0.04	0	0	1	0.04	0	0	0	0

Covid-19 pneumonia	0	0	6	0.23	0	0	5	0.22	0	0	1	0.30
Diverticulitis	0	0	2	0.08	0	0	2	0.09	0	0	0	0
Groin abscess	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Pneumonia fungal	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Streptococcal bacteremia	0	0	1	0.04	0	0	0	0	0	0	1	0.30
Viral infection	1	0.02	0	0.00	1	0.02	0	0.00	0	0	0	0
Cardiac disorders	**30**	**0.57**	**14**	**0.54**	**16**	**0.35**	**10**	**0.44**	**14**	**2.01**	**4**	**1.19**
Atrial fibrillation	7	0.13	2	0.08	4	0.09	1	0.04	3	0.43	1	0.30
Myocardial infarction	4	0.08	2	0.08	2	0.04	1	0.04	2	0.29	1	0.30
Acute left ventricular failure	3	0.06	0	0	1	0.02	0	0	2	0.29	0	0
Cardiac arrest	3	0.06	3	0.11	2	0.04	3	0.13	1	0.14	0	0
Cardiac failure congestive	3	0.06	1	0.04	1	0.02	1	0.04	2	0.29	0	0
Acute myocardial infarction	2	0.04	2	0.08	2	0.04	1	0.04	0	0	1	0.30
Angina pectoris	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Bradycardia	1	0.02	0	0	0	0	0	0	1	0.14	0	0
Cardiac pseudoaneurysm	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Coronary artery disease	1	0.02	2	0.08	1	0.02	1	0.04	0	0	1	0.30
Myocardial ischemia	1	0.02	0	0	0	0	0	0	1	0.14	0	0
Myocarditis	1	0.02	1	0.04	0	0	1	0.04	1	0.14	0	0
Palpitations	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Ventricular tachycardia	1	0.02	0	0	0	0	0	0	1	0.14	0	0
Cardio-respiratory arrest	0	0	1	0.04	0	0.00	1	0.04	0	0	0	0
Injury, poisoning, and procedural complications	**25**	**0.47**	**14**	**0.54**	**18**	**0.39**	**13**	**0.57**	**7**	**1.01**	**1**	**0.30**
Alcohol poisoning	2	0.04	1	0.04	2	0.04	1	0.04	0	0	0	0
Femur fracture	2	0.04	0	0	0	0	0	0	2	0.29	0	0
Rib fracture	2	0.04	1	0.04	1	0.02	1	0.04	1	0.14	0	0
Accidental overdose	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Ankle fracture	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Burns third degree	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Concussion	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Exposure to toxic agent	1	0.02	0	0	0	0	0	0	1	0.04	0	0
Fall	1	0.02	2	0.08	1	0.02	1	0.04	0	0	1	0.30
Fibula fracture	1	0.02	1	0.04	1	0.02	1	0.04	0	0	0	0
Gunshot wound	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Hip fracture	1	0.02	0	0	0	0	0	0	1	0.14	0	0
Incisional hernia	1	0.02	0	0	1	0.02	0	0	0	0	0	0

Jaw fracture	1	0.02	0	0	0	0	0	0	1	0.14	0	0
Overdose	1	0.02	2	0.08	1	0.02	2	0.09	0	0	0	0
Radius fracture	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Snake bite	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Spinal fracture	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Splenic rupture	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Tibia fracture	1	0.02	1	0.04	1	0.02	1	0.04	0	0	0	0
Traumatic hematoma	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Wrist fracture	1	0.02	0	0	0	0	0	0	1	0.14	0	0
Foot fracture	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Foreign body in gastrointestinal tract	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Injury	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Joint injury	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Lumbar vertebral fracture	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Road traffic accident	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Nervous system disorders	**19**	**0.36**	**9**	**0.34**	**16**	**0.35**	**8**	**0.35**	**3**	**0.43**	**1**	**0.30**
Cerebrovascular accident	7	0.13	1	0.04	5	0.11	0	0	2	0.29	1	0.30
Ischemic stroke	2	0.04	0	0	1	0.02	0	0	1	0.14	0	0
Seizure	2	0.04	1	0.04	2	0.04	1	0.04	0	0	0	0
Alcoholic seizure	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Altered state of consciousness	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Central nervous system inflammation	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Cervicogenic headache	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Neuropathy peripheral	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Peroneal nerve palsy	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Presyncope	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Transient ischemic attack	1	0.02	1	0.04	1	0.02	1	0.04	0	0	0	0
Carotid artery stenosis	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Cerebellar infarction	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Generalized tonic-clonic seizure	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Hypoesthesia	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Syncope	0	0	2	0.08	0	0	2	0.09	0	0	0	0
Gastrointestinal disorders	**16**	**0.30**	**6**	**0.23**	**14**	**0.31**	**4**	**0.18**	**2**	**0.29**	**2**	**0.59**
Intestinal obstruction	2	0.04	0	0	2	0.04	0	0	0	0	0	0
Abdominal pain	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Alcoholic pancreatitis	1	0.02	0	0	1	0.02	0	0	0	0	0	0

Ascites	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Colitis ulcerative	1	0.02	0	0	0	0	0	0	1	0.14	0	0
Gastritis	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Gastrointestinal hemorrhage	1	0.02	0	0	0	0	0	0	1	0.14	0	0
Hematemesis	1	0.02	1	0.04	1	0.02	1	0.04	0	0	0	0
Hiatus hernia	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Impaired gastric emptying	1	0.02	1	0.04	1	0.02	1	0.04	0	0	0	0
Mallory-Weiss syndrome	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Pancreatitis	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Pancreatitis acute	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Peptic ulcer	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Rectal hemorrhage	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Duodenal ulcer	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Gastric hemorrhage	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Nausea	0	0	1	0.04	0	0	0	0	0	0	1	0.30
Vomiting	0	0	1	0.04	0	0	0	0	0	0	1	0.30
Respiratory, thoracic, and mediastinal disorders	**16**	**0.30**	**8**	**0.31**	**11**	**0.24**	**5**	**0.22**	**5**	**0.72**	**3**	**0.89**
Acute respiratory failure	3	0.06	0	0	1	0.02	0	0	2	0.29	0	0
Pneumonia aspiration	3	0.06	0	0	3	0.07	0	0	0	0	0	0
Pulmonary embolism	3	0.06	2	0.08	1	0.02	1	0.04	2	0.29	1	0.30
Chronic obstructive pulmonary disease	2	0.04	0	0	1	0.02	0	0	1	0.14	0	0
Dyspnea	2	0.04	2	0.08	2	0.04	1	0.04	0	0	1	0.30
Asthma	1	0.02	2	0.08	1	0.02	1	0.04	0	0	1	0.30
Pulmonary hypertension	1	0.02	0	0.00	1	0.02	0	0	0	0	0	0
Respiratory failure	1	0.02	1	0.04	1	0.02	1	0.04	0	0	0	0
Pneumothorax	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Neoplasms benign, malignant, and unspecified (including cysts and polyps)	**14**	**0.27**	**4**	**0.15**	**8**	**0.17**	**4**	**0.18**	**6**	**0.86**	**0**	**0**
Prostate cancer	6	0.11	0	0	2	0.04	0	0	4	0.58	0	0
Breast cancer	2	0.04	0	0	2	0.04	0	0	0	0	0	0
Breast cancer metastatic	1	0.02	0	0	0	0	0	0	1	0.14	0	0
Breast cancer stage III	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Chronic myeloid leukemia	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Malignant melanoma	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Non-Hodgkin's lymphoma	1	0.02	0	0	0	0	0	0	1	0.14	0	0
Testis cancer	1	0.02	0	0	1	0.02	0	0	0	0	0	0

Anal squamous cell carcinoma	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Endometrial adenocarcinoma	0	0	2	0.08	0	0	2	0.09	0	0	0	0
Invasive ductal breast carcinoma	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Vascular disorders	**12**	**0.23**	**4**	**0.15**	**8**	**0.17**	**4**	**0.18**	**4**	**0.58**	**0**	**0**
Hypertension	3	0.06	0	0	3	0.07	0	0	0	0	0	0
Deep vein thrombosis	2	0.04	0	0	0	0	0	0	2	0.29	0	0
Hypertensive crisis	1	0.08	2	0.08	1	0.02	2	0.09	0	0	0	0
Arterial occlusive disease	1	0.02	0	0	0	0	0	0	1	0.14	0	0
Circulatory collapse	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Hematoma	1	0.02	0	0	0	0	0	0	1	0.14	0	0
Intermittent claudication	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Embolism	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Hypotension	2	0.04	1	0.04	2	0.04	1	0.04	0	0	0	0
Hepatobiliary disorders	**11**	**0.21**	**0**	**0**	**11**	**0.24**	**0**	**0**	**0**	**0**	**0**	**0**
Cholecystitis acute	5	0.09	0	0	5	0.11	0	0	0	0	0	0
Bile duct stone	2	0.04	0	0	2	0.04	0	0	0	0	0	0
Cholecystitis	2	0.04	0	0	2	0.04	0	0	0	0	0	0
Cholelithiasis	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Cirrhosis alcoholic	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Psychiatric disorders	**11**	**0.21**	**8**	**0.31**	**11**	**0.24**	**6**	**0.26**	**0**	**0**	**2**	**0.59**
Suicidal ideation	3	0.06	3	0.11	3	0.07	2	0.09	0	0	1	0.30
Bipolar disorder	2	0.04	1	0.04	2	0.04	0	0	0	0	1	0.30
Depression	2	0.04	0	0	2	0.04	0	0	0	0	0	0
Drug abuse	1	0.02	1	0.04	1	0.02	1	0.04	0	0	0	0
Homicidal ideation	1	0.02	0	0.00	1	0.02	0	0.00	0	0	0	0
Psychiatric symptom	1	0.02	0	0.00	1	0.02	0	0.00	0	0	0	0
Substance abuse	1	0.02	0	0.00	1	0.02	0	0.00	0	0	0	0
Alcohol abuse	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Delusion	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Panic attack	0	0	1	0.04	0	0	1	0.04	0	0	0	0
General disorders and administration site conditions	**7**	**0.13**	**6**	**0.23**	**3**	**0.07**	**4**	**0.18**	**4**	**0.58**	**2**	**0.59**
Asthenia	2	0.04	0	0	0	0	0	0	2	0.29	0	0
Chest pain	1	0.02	3	0.11	1	0.02	2	0.09	0	0	1	0.30
Drug withdrawal syndrome	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Mucosal inflammation	1	0.02	0	0	0	0	0	0	1	0.14	0	0
Edema peripheral	1	0.02	1	0.04	0	0	1	0.04	1	0.14	0	0

Sudden death	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Catheter site thrombosis	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Edema	0	0	1	0.04	0	0	0	0	0	0	1	0.30
Musculoskeletal and connective tissue disorders	**7**	**0.13**	**2**	**0.08**	**4**	**0.09**	**2**	**0.09**	**3**	**0.43**	**0**	**0**
Intervertebral disc protrusion	2	0.04	0	0	1	0.02	0	0	1	0.14	0	0
Arthralgia	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Cervical spinal stenosis	1	0.02	0	0	1	0.02	0	0	**0**	**0**	0	0
Osteoarthritis	1	0.02	0	0	0	0	0	0	1	0.14	0	0
Osteolysis	1	0.02	0	0	0	0	0	0	1	0.14	0	0
Rhabdomyolysis	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Intervertebral disc disorder	0	0	1	0.04	0	0	1	0.04			0	0
Neck pain	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Pregnancy, puerperium, and perinatal conditions	**6**	**0.11**	**1**	**0.04**	**6**	**0.13**	**1**	**0.04**	**0**	**0**	**0**	**0**
Abortion spontaneous	3	0.06	1	0.04	3	0.07	1	0.04	0	0	0	0
Pregnancy	2	0.04	0	0	2	0.04	0	0	0	0	0	0
Abortion spontaneous complete	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Blood and lymphatic system disorders	**5**	**0.09**	**1**	**0.04**	**4**	**0.09**	**1**	**0.04**	**1**	**0.14**	**0**	**0**
Blood loss anemia	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Iron deficiency anemia	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Neutropenia	1	0.02	0	0	0	0	0	0	1	0.14	0	0
Normocytic anemia	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Thrombocytopenia	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Leukocytosis	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Renal and urinary disorders	**4**	**0.08**	**4**	**0.15**	**2**	**0.04**	**3**	**0.13**	**2**	**0.29**	**1**	**0.30**
Acute kidney injury	2	0.04	1	0.04	1	0.02	1	0.04	1	0.14	0	0
Chronic kidney disease	1	0.02	0	0	0	0	0	0	1	0.14	0	0
Nephrolithiasis	1	0.02	2	0.08	1	0.02	2	0.09	0	0	0	0
Renal failure	0	0	1	0.04	0	0	0	0	0	0	1	0.30
Endocrine disorders	**3**	**0.06**	**0**	**0**	**3**	**0.07**	**0**	**0**	**0**	**0**	**0**	**0**
Basedow's disease	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Hyperparathyroidism	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Hyperthyroidism	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Metabolism and nutrition disorders	**3**	**0.06**	**7**	**0.27**	**3**	**0.07**	**7**	**0.31**	**0**	**0**	**0**	**0**
Diabetic ketoacidosis	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Electrolyte imbalance	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Type 2 diabetes mellitus	1	0.02	0	0	1	0.02	0	0	0	0	0	0

Dehydration	0	0	2	0.08	0	0	2	0.09	0	0	0	0
Hyperglycemia	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Hypoglycemia	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Hypokalemia	0	0	2	0.08	0	0	2	0.09	0	0	0	0
Hyponatremia	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Skin and subcutaneous tissue disorders	**2**	**0.04**	**0**	**0**	**1**	**0.02**	**0**	**0**	**1**	**0.14**	**0**	**0**
Angioedema	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Dermatitis	1	0.02	0	0	0	0	0	0	1	0.14	0	0
Uncoded	**2**	**0.04**	**0**	**0**	**2**	**0.04**	**0**	**0**	**0**	**0**	**0**	**0**
Cholecystitis and cholelithiasis	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Syncope leading to focal seizure disorder	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Eye disorders	**1**	**0.02**	**0**	**0**	**1**	**0.02**	**0**	**0**	**0**	**0**	**0**	**0**
Diplopia	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Surgical and medical procedures	**1**	**0.02**	**2**	**0.08**	**1**	**0.02**	**1**	**0.04**	**0**	**0**	**1**	**0.30**
Coronary arterial stent insertion	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Hip arthroplasty	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Spinal fusion surgery	0	0	1	0.04	0	0	0	0	0	0	1	0.30
Investigations	**0**	**0**	**2**	**0.08**	**0**	**0**	**2**	**0.09**	**0**	**0**	**0**	**0**
Oxygen saturation decreased	0	0	1	0.04	0	0	1	0.04	0	0	0	0
SARS-CoV-2 test positive	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Reproductive system and breast disorders	**0**	**0**	**1**	**0.04**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0.30**
Benign prostatic hyperplasia	0	0	1	0.04	0	0	0	0	0	0	1	0.30

Abbreviations: E = number of AEs reported; IR = incidence rate is defined as number of events per 100 person-years = e/100 PY; MedDRA = Medical Dictionary for Regulatory Activities; NVX-CoV2373 = 5 μg SARS-CoV-2 rS with 50 μg Matrix-M™ adjuvant; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine.

Table S16. Serious AEs of Interest Reported in PREVENT-19, Including Safety Signals Observed During Use of Other Covid-19 Vaccines (Safety Analysis Set)

System Organ Class/ Preferred Term (MedDRA, Version 23.1)	Participants ≥18 Years				Participants 18 to ≤64 Years				Participants ≥65 Years			
	NVX-CoV2373 N = 19,729		Placebo N = 9853		NVX-CoV2373 N = 17,251		Placebo N = 8616		NVX-CoV2373 N = 2478		Placebo N = 1237	
	E	IR	E	IR	E	IR	E	IR	E	IR	E	IR
Cardiac disorders												
Myocardial infarction	4	0.08	2	0.08	2	0.04	1	0.04	2	0.29	1	0.30
Myocarditis	1	0.02	1	0.04	0	0	1	0.04	1	0.14	0	0
Pericarditis	0	0	0	0	0	0	0	0	0	0	0	0
Respiratory, thoracic, and mediastinal disorders												
Pulmonary embolism	3	0.06	2	0.08	1	0.02	1	0.04	2	0.29	1	0.30
Vascular disorders												
Deep vein thrombosis	2	0.04	0	0	0	0	0	0	2	0.29	0	0
Embolism	0	0	1	0.04	0	0	1	0.04	0	0	0	0
Cerebral venous sinus thrombosis	0	0	0	0	0	0	0	0	0	0	0	0
Blood and lymphatic system disorders												
Thrombocytopenia	1	0.02	0	0	1	0.02	0	0	0	0	0	0
Disseminated intravascular coagulation	0	0	0	0	0	0	0	0	0	0	0	0
Immune system disorders												
Guillain-Barré syndrome	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: E = number of AEs reported; IR = incidence rate is defined as number of events per 100 person-years = e/100 PY; MedDRA = Medical Dictionary for Regulatory Activities; NVX-CoV2373 = 5 μg SARS-CoV-2 rS with 50 μg Matrix-M™ adjuvant; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine.

Table S17. Vaccine Efficacy Against RT-PCR-Confirmed Symptomatic Mild, Moderate, or Severe Covid-19 at Least 7 Days After Second Vaccination in Adult Participants (Full Analysis Set)

Parameter	NVX-CoV2373 N = 18,584	Placebo N = 9,144
Participants with no occurrence of event,* n (%)	18,568	9075
Participants with occurrence of event,† n (%)	16	69
Severity of first occurrence, n (%)		
Mild	15	54
Moderate	1	11
Severe	0	4
Median surveillance time‡ (days)	64	60
Log-linear model using modified Poisson regression§		
Mean disease incidence rate per year in 1000 people	3.69	34.55
95% CI	1.83, 7.44	22.25, 53.64
Relative risk	0.11	
95% CI	0.06, 0.18	
Vaccine efficacy (%)	89.31	
95% CI	81.59, 93.79	
P-value‖	<0.001	

Abbreviations: CI = confidence interval; Covid-19 = coronavirus disease 2019; NVX-CoV2373 = 5 µg SARS-CoV-2 rS with 50 µg Matrix-M™ adjuvant; RT-PCR = reverse transcriptase-polymerase chain reaction; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine; VE = vaccine efficacy.

* Includes participants with RT-PCR-confirmed infection who did not meet mild, moderate, or severe Covid-19 criteria.

† Event = first occurrence of RT-PCR-confirmed mild, moderate, or severe Covid-19 with onset of illness episode from at least 7 days after second vaccination within the surveillance period.

‡ Surveillance time was defined as the difference between the date at end of surveillance period (onset of first occurrence of event/ censoring) and date at start of surveillance period (7 days after the second injection) + 1.

§ Modified Poisson regression with logarithmic link function, treatment group, and age strata as fixed effects and robust error variance.[6]

‖ This P-value corresponded to a one-sided hypothesis test with significance level 0.025. If the VE P-value <0.025, then reject H0: VE ≤0%.

Table S18. Specific reasons for exclusion of participants from the per-protocol analysis set (PP-EFF)

Baseline reasons
• 58 (0.3%) active subjects in the ITT were never treated • 23 (0.2%) of placebo subjects in the ITT were never treated • 1,239 (6.3%) active subjects in the FAS were anti-NP or PCR positive at baseline • 676 (6.9%) of placebo subjects in the FAS were anti-NP or PCR positive at baseline
On-study reasons

• 643 (3.3%) active subjects in the FAS did not receive two vaccine doses
• 452 (4.6%) placebo subjects in the FAS did not receive two placebo doses
• 1 (0.01%) active subject in the FAS were dosed out of window
• 3 (0.03%) placebo subjects in the FAS were dosed out of window
• 164 (0.8%) active subjects in the FAS had a protocol deviation before 7 days post dose 2
  o 102 (0.5%) active subjects in the FAS had a dosing non-compliance protocol deviation
  o 47 (0.2%) active subjects in the FAS took a prohibited medication
  o 17 (0.1%) active subjects in the FAS had a different protocol deviation, unrelated to dosing non-compliance/prohibited medications
• 460 (4.7%) placebo subjects in the FAS had a protocol deviation before 7 days post dose 2
  o 347 (3.5%) placebo subjects in the FAS had a dosing non-compliance protocol deviation
  o 116 (1.2%) placebo subjects in the FAS took a prohibited medication
  o 24 (0.2%) placebo subjects in the FAS had a different protocol deviation, unrelated to dosing non-compliance/prohibited medications
• 322 (1.6%) active subjects in the FAS were unblinded before 7 days post dose 2
• 184 (1.9%) placebo subjects in the FAS were unblinded before 7 days post dose 2
• 486 (2.5%) active subjects in the FAS were censored before 7 days post dose 2 NOT due to a protocol deviation
• 238 (2.4%) placebo subjects in the FAS were censored before 7 days post dose 2 NOT due to a protocol deviation

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