# 2.5 Clinical Overview

## Version 1.0 dated 17 August 2021



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# LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

| | |
|---|---|
| 2019-nCoV | Novel coronavirus |
| AE | Adverse event |
| AESI | Adverse event(s) of special interest |
| Anti-N | Anti-nucleocapsid |
| aTIV | Adjuvanted trivalent influenza vaccine |
| BMI | Body mass index |
| CDC | Centers for Disease Control and Prevention |
| CI | Confidence interval |
| CMI | Cell-mediated immunity |
| COFEPRIS | Federal Commission for Protection against Sanitary Risks |
| COVID-19 | Coronavirus disease 2019 |
| DP | Drug product |
| DS | Drug substance |
| DSMB | Data and Safety Monitoring Board |
| e/100 PY | Events per 100 person-years |
| EBSI | Emergent BioSolutions |
| eCRF | Electronic case report form |
| EMA | European Medicines Agency |
| ERC | Independent Endpoint Review Committee |
| EUA | Emergency use authorization |
| FDBU | FujiFilm Diosynth Biotechnologies |
| GCP | Good Clinical Practice |
| GLP | Good Laboratory Practice |
| hACE2 | Human angiotensin-converting enzyme 2 |
| HAI | Hemagglutination inhibition |
| HR1 | Heptad repeat 1 |
| HIV | Human immunodeficiency virus |
| LBCI | Lower bound confidence interval |
| IgG | Immunoglobulin G |
| IM | Intramuscular |
| IR | Incidence rate |

| | |
|---|---|
| LLOQ | Lower limit of quantitation |
| MAAE | Medically attended adverse event |
| MedDRA | Medical Dictionary for Regulatory Activities |
| MERS | Middle East Respiratory Syndrome |
| MHC | Major histocompatibility complex |
| MHRA | Medicines and Healthcare products Regulatory Agency |
| mRNA | Messenger ribonucleic acid |
| NVX-CoV2373 | 5 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant |
| PCR | Polymerase chain reaction |
| PHEIC | Public health emergency of international concern |
| PIMMC | Potential immune-mediated medical condition |
| PP-EFF | Per-Protocol Efficacy |
| PP-EFF-2 | Per-Protocol Efficacy 2 |
| QIVc | Quadrivalent influenza vaccine (unadjuvanted) |
| r | Recombinant |
| RBD | Receptor-binding domain |
| RNA | Ribonucleic acid |
| S | Spike (protein) |
| SAE | Serious adverse event |
| SARS-CoV | Severe acute respiratory syndrome coronavirus |
| SARS-CoV-2 | Severe acute respiratory syndrome coronavirus 2 |
| SARS-CoV-2 rS | Severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine |
| Sf9 | *Spodoptera frugiperda* |
| SMC | Safety monitoring committee |
| TEAE | Treatment-emergent adverse event |
| TGA | Therapeutic Goods Administration |
| Th1 | Type 1 T helper |
| Th2 | Type 2 T helper |
| UK | United Kingdom |
| ULOQ | Upper limit of quantitation |
| US | United States |

| | |
|---|---|
| US FDA | United States Food and Drug Administration |
| VE | Vaccine efficacy |
| VOC | Variant of Concern |
| VOI | Variant of Interest |
| WHO | World Health Organization |

# 2.5.1 PRODUCT DEVELOPMENT RATIONALE

## 2.5.1.1 Product and Proposed Indication

Novavax is developing a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) recombinant (r) spike (S) protein nanoparticle vaccine (SARS-CoV-2 rS) with Matrix-M adjuvant for the proposed indication of active immunization for the prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2. SARS-CoV-2 rS (5 µg per dose) with Matrix-M adjuvant (50 µg per dose) is intended for intramuscular (IM) administration (0.5 mL) on Days 0 and 21 (+ 7 days) in humans. For the purposes of clinical documents, 5 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant is referred to as NVX-CoV2373. It is also noted that Matrix-M adjuvant has previously been referred to as Matrix-M1 adjuvant throughout various documents; Matrix-M adjuvant is used herein and is the nomenclature planned for future use.

The SARS-CoV-2 rS vaccine is constructed from the full-length, wild-type SARS-CoV-2 S glycoprotein based upon the GenBank gene sequence MN908947 (Wuhan-Hu-1 isolate) nucleotides 21563-25384. The S protein is a Type 1 trimeric glycoprotein of 1,273 amino acids that is produced as an inactive S0 precursor. To produce the SARS-CoV-2 rS vaccine candidate, the *S* gene was codon optimized for expression in *Spodoptera frugiperda* (Sf9) insect cells. The native full-length S protein was modified by mutation of the putative furin cleavage site RRAR to QQAQ located within the S1/S2 cleavage domain (3Q) to be protease resistant. Two additional proline amino acid substitutions were inserted at positions K986P and V987P (2P) within the heptad repeat 1 (HR1) domain to stabilize SARS-CoV-2 S in a prefusion conformation, which is believed to optimize presentation of neutralizing epitopes [Wrapp 2020]. The synthetic transgene has been engineered into the baculovirus vector (construct BV2373) for expression in Sf9 insect cells. Purified SARS-CoV-2 rS protein trimers are uncleaved, thermostable at elevated temperatures (maximum temperature > 60ºC), and specifically bind to the human angiotensin-converting enzyme 2 (hACE2) receptor, the receptor used by SARS-CoV-2 to attach to human cells, with high affinity [Tian 2021].

The SARS-CoV-2 rS vaccine will be co-administered with the saponin-based Matrix-M adjuvant. Matrix-M adjuvant, developed at Novavax AB (Uppsala, Sweden), is derived from fractionated Quillaja saponins, phosphatidylcholine, and cholesterol formulated into ~40 nm cage-like structures. Quillaja saponins are extracted from the bark of the tree *Quillaja saponaria* Molina in a multi-step process before being mixed with cholesterol and phospholipids using a proprietary method to create the matrix particles. The proposed mode of action for saponin-based adjuvants like Matrix-M does not include a depot effect, but rather is through a combination of activities including recruitment and activation of innate immune cells, rapid antigen delivery to antigen presenting cells, and enhanced antigen presentation via both major histocompatibility complex (MHC) I and II molecules in the draining lymph nodes [Lovgren-Bengtsson 2000, Reimer 2012]. A literature review and discussion of pharmacology data for the Matrix-M adjuvant is provided Module 2.4.1.3.

### 2.5.1.2 COVID-19 Background

Coronaviruses are medium sized, enveloped, positive-stranded ribonucleic acid (RNA) viruses, with a characteristic crown-like appearance in electron micrographs due to circumferential studding of the viral envelope with projections comprising the S protein. There are 4 different strains of coronaviruses (229E, OC43, NL63, and HKU1), which are ubiquitous in humans and generally result in mild upper respiratory illnesses and other common cold symptoms including malaise, headache, nasal discharge, sore throat, fever, and cough [Su 2016]. In addition, other coronavirus strains are widespread in animals, where they typically cause enteric disease. These zoonotic coronaviruses have been known to evolve into strains that can infect humans with serious consequences including severe acute respiratory syndrome coronavirus (SARS-CoV) from 2002 to 2003, Middle East Respiratory Syndrome (MERS)-CoV since 2012, and most recently, the novel SARS-CoV-2 since 2019 [Habibzadeh 2020].

In late December of 2019, an outbreak of respiratory disease caused by novel coronavirus (2019-nCoV) was detected in Wuhan, Hubei province, China. The virus' rapidly discerned genetic relationship with the 2002-2003 SARS-CoV has resulted in adoption of the name "SARS-CoV-2," with the disease being referred to as COVID-19. Despite containment efforts since the start of the outbreak, the SARS-CoV-2 has spread rapidly. On 30 January 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) designated the outbreak as a public health emergency of international concern (PHEIC) and subsequently declared a pandemic on 11 March 2020 [Cucinotta 2020].

Following essentially worldwide spread of the original SARS-CoV-2 strain, more recent reports from the United Kingdom (UK), Brazil, South Africa, and India have revealed the emergence of the B.1.1.7 (Alpha), P.1 (Gamma), B.1.351 (Beta), and B.1.617.2 (Delta) variants of SARS-CoV-2, respectively, with confirmed acquisition of mutations in key antigenic sites in the receptor-binding domain (RBD) and N-terminal domain of the S protein. Intense transmission during the first wave in South Africa, high levels of resulting population immunity to prototype viruses and conditions sustaining a high force of infection in advance of the second wave may have created a milieu favorable to the emergence of the B.1.351 (Beta) variant [Cele 2021, Greaney 2021, Sabino 2021, Tegally 2021, Volz 2021, Ho 2021]. These conditions, which are present in other settings, may indicate that novel variants will continue to appear.

The B.1.351 (Beta) variant is reported to have emerged in the Eastern Cape Province, South Africa, in October 2020, and rapidly spread to become the dominant circulating strain throughout the country during November and December 2020 coincident with the surge of the second wave of transmission nationally [Tegally 2021]. The B.1.351 (Beta) variant is characterized by 3 deleterious mutations at key antigenic sites in the RBD, including N501Y, K417N, and E484K, with the latter two having particular antibody functional significance [Greaney 2021, Tegally 2021, Ho 2021, Wang 2021]. The N501Y mutation is known to increase binding affinity of the S protein to the hACE2 receptor [Starr 2020] and has been reported to increase transmissibility of the B.1.1.7 (Alpha) variant circulating in the UK [Volz 2021]. The E484K mutation has been reported to abolish or substantially reduce neutralization by multiple potent monoclonal antibodies and polyclonal convalescent sera in

both wild-type virus and pseudovirus neutralization assays [Cele 2021, Greaney 2021, Ho 2021, Wang 2021, Wibmer 2021]. Additionally, post-vaccination sera derived from volunteers receiving either of the messenger RNA (mRNA) vaccines has also been reported to show 6.5- to 8.6-fold reductions in neutralizing capacity to the B.1.351 (Beta) variants relative to prototype virus in pseudovirus neutralization [Ho 2021], however, the impact on clinical efficacy for mRNA vaccines remains unclear.

Reduced clinical efficacy against the B.1.351 (Beta) variant for more traditional viral vector COVID-19 vaccines, however, has been observed [Johnson 2021, Madhi 2021]. More recently, increased transmission of the B.1.617.2 (Delta) variant, first identified in India, has been noted in a number of countries worldwide and this strain was listed as Variant of Concern (VOC) by the WHO on 11 May 2021 [WHO 2021a]. The B.1.617.2 (Delta) variant has mutations in the SARS-CoV-2 S protein resulting in substitutions at the T478K and L452R positions in the RBD that are known to affect the transmissibility of the virus and are also associated with reduced neutralization by vaccine sera [CDC 2021]. Additionally, a further variant, termed Lambda, is currently emerging in South America and features a different suite of mutations that may also both augment transmission and reduce the efficacy of existing vaccine-induced immune responses [Kimura 2021].

### 2.5.1.3 Clinical Development Program

Table 2.5-1 describes the clinical studies included in the SARS-CoV-2 rS vaccine clinical development program sponsored by Novavax and summarized herein. The clinical development program for SARS-CoV-2 rS with Matrix-M adjuvant comprises 5 ongoing clinical studies:

| | |
|---|---|
| 2019nCoV-101 (Part 1): | A 2-Part, Phase 1/2, Randomized, Observer-Blinded Study to Evaluate the Safety and Immunogenicity of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) With or Without Matrix-M™ Adjuvant in Healthy Subjects. *Note: This is Part 1(Phase 1 first-in-human) of 2019nCoV-101 evaluating participants 18 to 59 years of age with and without adjuvant and evaluated as a bedside-mixed antigen and adjuvant.* |
| 2019nCoV-101 (Part 2): | A 2-Part, Phase 1/2, Randomized, Observer-Blinded Study to Evaluate the Safety and Immunogenicity of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) With or Without Matrix-M™ Adjuvant in Healthy Subjects. *Note: This is Part 2 (Phase 2) of 2019nCoV-101 evaluating participants 18 to 84 years of age with adjuvant and evaluated co-formulated drug product (DP) (as in the remaining Phase 2 and Phase 3 studies).* |

| | |
|---|---|
| 2019nCoV-501: | A Phase 2a/b, Randomized, Observer-Blinded, Placebo-Controlled Study to Evaluate the Efficacy, Immunogenicity, and Safety of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) With Matrix-M™ Adjuvant in South African Adult Subjects Living Without HIV; and Safety and Immunogenicity in Adults Living With HIV |
| 2019nCoV-302: | A Phase 3, Randomised, Observer-Blinded, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with Matrix-M™ Adjuvant in Adult Participants 18-84 Years of Age in the United Kingdom |
| 2019nCoV-301: | A Phase 3, Randomized, Observer-Blinded, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with Matrix-M™ Adjuvant in Adult Participants ≥ 18 Years with a Pediatric Expansion in Adolescents (12 to < 18 Years) |

Enrollment and primary vaccination (ie, Days 0 and 21 [+ 7 days]) have been completed in all studies, and follow-up is ongoing. Six-month safety and immunogenicity data are available in Part 1 (Phase 1) of Clinical Study 2019nCoV-101, and Day 35 safety and immunogenicity data are available in Part 2 (Phase 2) of Clinical Study 2019nCoV-101. Final primary efficacy endpoint and safety analyses have been conducted in Clinical Studies 2019nCoV-501, 2019nCoV-302, and 2019nCoV-301 with a median duration of at least 60 days of safety follow-up in Clinical Studies 2019nCoV-302 and 2019nCoV-301. Immunogenicity data through Day 35 are also available for Clinical Studies 2019nCoV-501 and 2019nCoV-302. Collectively, these data are intended to support initial approval for the primary vaccination series (ie, Days 0 and 21 [+7 days]) in adults ≥ 18 years of age via emergency, conditional, or provisional applications as appropriate. A summary of a pooled safety analysis of the aforementioned studies is provided in Section 2.5.6.7.

It is noted that booster data are not available in Clinical Studies 2019nCoV-101 (Part 2) or 2019nCoV-501, and blinded crossover data are not available in Clinical Studies 2019nCoV-501, 2019nCoV-302, and 2019nCoV-301. In addition, pediatric data are not yet available in Clinical Study 2019nCoV-301. These additional data are intended to be filed in subsequent amendments or variations following initial approval as these data become available, including additional safety, immunogenicity, and efficacy data (ie, through 6 months and 1 year) to support full approval, as well as booster data and pediatric data, to support future additional label claims. Lastly, clinical data from studies evaluating SARS-CoV-2 rS with Matrix-M adjuvant sponsored by partners (eg, Serum Institute of India and Takeda) conducted in region-specific studies (eg, India and Japan, respectively) or investigator-initiated trials are not provided herein given study status and data availability. No unique safety issues have been reported to Novavax from any of these trials to date.

**Table 2.5-1: Ongoing Novavax-Sponsored Clinical Studies with SARS-CoV-2 rS Vaccine with or without Matrix-M Adjuvant in the SARS-CoV-2 rS Vaccine Clinical Development Program**

| Clinical Study Number (Country) | Study Design | Primary Endpoints | Dosage, Duration and Dosage Regimen | Planned (Treated) Number of Subjects | Study Status[1] | Cross-References |
|---|---|---|---|---|---|---|
| 2019nCoV-101 – Part 1 (Australia) | Phase 1, randomized, observer-blinded, placebo-controlled in healthy adults ≥ 18 to ≤ 59 years of age | Safety<br>Immunogenicity | Dose 1 (Day 0)/Dose 2 (Day 21)[2]<br>A: Placebo/ Placebo<br>B: 25 µg+0 µg/ 25 µg+0 µg<br>C: 5 µg+50 µg/ 5 µg+50 µg<br>D: 25 µg+50 µg/ 25 µg+50 µg<br>E: 25 µg + 50 µg/ Placebo<br><br>IM injection on Days 0 and 21 (+ 7 days); antigen and adjuvant were administered as a bedside mixture | Total: 131 (131)<br>A: 25 (23)<br>B: 25 (25)<br>C: 28 (29)<br>D: 28 (28)<br>E: 25 (26) | Ongoing (enrollment and treatment complete); Day 35 and Day 189 interim analyses complete | Protocol (Version 8.0 – dated 17 Dec 2020)<br><br>Statistical analysis plan (Version 2.1 – dated 17 Dec 2020)<br><br>Interim study report through Day 189 (Version 1.0 – dated 25 Feb 2021)<br><br>Publication ([Keech 2020]) |

**Table 2.5-1: Ongoing Novavax-Sponsored Clinical Studies with SARS-CoV-2 rS Vaccine with or without Matrix-M Adjuvant in the SARS-CoV-2 rS Vaccine Clinical Development Program**

| Clinical Study Number (Country) | Study Design | Primary Endpoints | Dosage, Duration and Dosage Regimen | Planned (Treated) Number of Subjects | Study Status[1] | Cross-References |
|---|---|---|---|---|---|---|
| 2019nCoV-101 – Part 2 (Australia and US) | Phase 2, randomized, observer-blinded, placebo-controlled in healthy adult subjects ≥ 18 to ≤ 84 years of age | Immunogenicity<br>Safety | Dose 1 (Day 0)/Dose 2 (Day 21)[2]<br>A: Placebo/ Placebo<br>B: 5 µg+50 µg/ 5 µg+50 µg<br>C: 5 µg+50 µg/ Placebo<br>D: 25 µg+50 µg/ 25 µg+50 µg<br>E: 25 µg+50 µg/ Placebo<br><br>Booster Dose 3 (Day 189)<br>A: Placebo<br>B1: Placebo<br>B2: 5 µg+50 µg<br>C1: Placebo<br>C2: 5 µg+50 µg<br>D: Placebo<br>E: 5 µg+50 µg<br><br>Booster Dose 4 (Day 357) (subset)<br>B1: 5 µg+50 µg<br>B2: 5 µg+50 µg<br>C1: 5 µg+50 µg<br>C2: Placebo<br><br>IM injection on Days 0 and 21 (+ 7 days) (primary) and Days 189 and 357 (booster); antigen and adjuvant were administered as a co-formulation | Total: 750-1,500 (1,283)<br><br>A: 150-300 (255)<br>B: 150-300 (258)<br>C: 150-300 (256)<br>D: 150-300 (259)<br>E: 150-300 (255) | Ongoing (enrollment and Dose 1, Dose 2, and Dose 3 complete and Day 357 booster dose planned); Day 35 interim analysis complete | Protocol (Version 8.0 – dated 17 Dec 2020)<br><br>Statistical analysis plan (Version 2.0 – dated 02 Dec 2020)<br><br>Interim study report through Day 35 (Version 1.0 – dated 10 Mar 2021)<br><br>Publications ([Formica 2021]) |

**Table 2.5-1: Ongoing Novavax-Sponsored Clinical Studies with SARS-CoV-2 rS Vaccine with or without Matrix-M Adjuvant in the SARS-CoV-2 rS Vaccine Clinical Development Program**

| Clinical Study Number (Country) | Study Design | Primary Endpoints | Dosage, Duration and Dosage Regimen | Planned (Treated) Number of Subjects | Study Status[1] | Cross-References |
|---|---|---|---|---|---|---|
| 2019nCoV-501 (South Africa) | Phase 2a/2b, randomized, observer-blinded, placebo-controlled in healthy adult HIV-negative subjects ≥ 18 to ≤ 84 years of age and in medically stable adult HIV-positive subjects ≥ 18 to ≤ 64 years of age.<br><br>Includes a blinded crossover vaccination period at 6 months post second dose of the initial vaccination period, where participants who received active vaccine in the Initial Set of Vaccinations will receive a booster dose of active vaccine on Day 0 and placebo on Day 21 (+ 7 days) of the Crossover Vaccination Period and participants who received placebo in the Initial Set of Vaccinations will receive active vaccine on Days 0 and 21 (+ 7 days) of the Crossover Vaccination Period.[4] | Efficacy<br>Immunogenicity<br>Safety | Initial Set of Vaccinations<br>5 µg SARS-CoV-2 rS + 50 µg Matrix-M adjuvant or Placebo<br><br>Crossover Set of Vaccinations<br>5 µg SARS-CoV-2 rS + 50 µg Matrix-M adjuvant or Placebo<br><br>IM injection on Days 0 and 21 (+ 7 days) of Initial and Crossover Vaccination Periods; antigen and adjuvant were administered as a co-formulation | Total: 2,960-4,164 (4,408)<br><br>SARS-CoV-2 rS: 1,480-2,082 (2,211 [2,089 HIV-negative/ 122 HIV-positive])<br>Placebo: 1,480-2,082 (2,197 [2,075 HIV-negative/ 122 HIV-positive]) | Ongoing (enrollment and initial vaccinations complete; crossover vaccinations complete); primary efficacy endpoint analysis complete | Protocol (Version 5.1 – dated 25 Feb 2021)<br><br>Statistical analysis plan (Version 2.0 – dated 28 Apr 2021)<br><br>Interim study report (Version 1.0 – dated 19 May 2021)<br><br>Publications ([Shinde 2021]) |

**Table 2.5-1: Ongoing Novavax-Sponsored Clinical Studies with SARS-CoV-2 rS Vaccine with or without Matrix-M Adjuvant in the SARS-CoV-2 rS Vaccine Clinical Development Program**

| Clinical Study Number (Country) | Study Design | Primary Endpoints | Dosage, Duration and Dosage Regimen | Planned (Treated) Number of Subjects | Study Status[1] | Cross-References |
|---|---|---|---|---|---|---|
| 2019nCoV-302 (UK) | A Phase 3, multicenter, randomized, observer-blinded, placebo-controlled study evaluating the efficacy, safety, and immunogenicity of SARS-CoV-2 rS with Matrix-M adjuvant in adult participants ≥ 18 to ≤ 84 years.<br><br>Includes an influenza vaccine co-administration substudy and a blinded crossover vaccination period initiated after achieving the primary efficacy endpoint.<br><br>In the Crossover Vaccination Period, participants will receive the alternate trial vaccine or placebo than received in the Initial Set of Vaccinations.[4] | Efficacy<br>Immunogenicity<br>Safety | Initial Set of Vaccinations<br>5 µg SARS-CoV-2 rS + 50 µg Matrix-M adjuvant or Placebo<br>Influenza vaccine (in a substudy of approximately 400 participants)<br><br>Crossover Set of Vaccinations<br>5 µg SARS-CoV-2 rS + 50 µg Matrix-M adjuvant or Placebo<br><br>IM injection on Days 0 (with influenza vaccine) and 21 (+ 7 days) of Initial and Crossover Vaccination Periods; antigen and adjuvant were administered as a co-formulation | Total: 15,000 (15,139)<br><br>SARS-CoV-2 rS: 7,500 (7,569)<br>Placebo: 7,500 (7,570) | Ongoing (enrollment and initial vaccinations complete and crossover vaccinations complete); primary efficacy analysis complete | Protocol (Version 4.0 – dated 25 Feb 2021)<br><br>Statistical analysis plan (Version 4.0 – dated 05 Mar 2021)<br><br>Interim study report for Main Study (Version 1.0 – dated 06 May 2021)<br><br>Interim study report for Flu Substudy (Version 1.0 – dated 02 Aug 2021)<br><br>Publications ([Heath 2021]) |

**Table 2.5-1: Ongoing Novavax-Sponsored Clinical Studies with SARS-CoV-2 rS Vaccine with or without Matrix-M Adjuvant in the SARS-CoV-2 rS Vaccine Clinical Development Program**

| Clinical Study Number (Country) | Study Design | Primary Endpoints | Dosage, Duration and Dosage Regimen | Planned (Treated) Number of Subjects | Study Status[1] | Cross-References |
|---|---|---|---|---|---|---|
| 2019nCoV-301 (US and Mexico) | A Phase 3, randomized, observer-blinded, placebo-controlled study to evaluate the efficacy, safety, and immunogenicity of SARS-CoV-2 rS with Matrix-M adjuvant in adult participants ≥ 18 years of age with a pediatric expansion (12 to < 18 years of age).<br><br>Includes a blinded crossover vaccination period for both adults and pediatric participants initiated after following collection of sufficient safety data to support an Application for Emergency Use Authorization (EUA).[5] In the Crossover Vaccination Period, participants will receive the alternate trial vaccine or placebo than received in the Initial Set of Vaccinations.[4] | Efficacy<br>Immunogenicity<br>Safety | Initial Set of Vaccinations<br>5 µg SARS-CoV-2 rS + 50 µg Matrix-M adjuvant or Placebo<br><br>Crossover Set of Vaccinations<br>5 µg SARS-CoV-2 rS + 50 µg Matrix-M adjuvant or Placebo<br><br>IM injection on Days 0 and 21 (+ 7 days) of Initial and Crossover Vaccination Periods; antigen and adjuvant were administered as a co-formulation | Adult Main Study:<br>Total: 30,000 (29,582)<br><br>SARS-CoV-2 rS: 20,000 (19,729)<br>Placebo: 10,000 (9,853)<br><br>Pediatric Expansion:[3]<br>Total: 3,000 (2,248) | Adult Main Study:<br>Ongoing (enrollment, initial and crossover vaccinations complete); primary efficacy analysis complete<br><br>Pediatric Expansion:<br>Ongoing (enrollment and initial vaccination complete, crossover vaccinations initiated) | Protocol (Version 9.0 – dated 14 May 2021)<br><br>Statistical analysis plan (Version 5.0 – dated 31 May 2021)<br><br>Interim study report (Version 1.0 – dated 09 Aug 2021) |

Abbreviations: COVID-19 = coronavirus disease 2019; FDA = United States Food and Drug Administration; HIV = human immunodeficiency virus; IM = intramuscular; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine; UK = United Kingdom; US = United States.

1. Study status as of 12 August 2021.
2. Dose regimens described as X µg + X µg represent the antigen (SARS-CoV-2 rS) dose + adjuvant (Matrix-M) dose.
3. Study remains blinded to individual vaccine assignment at the participant level.
4. Data for the blinded crossover portion of Clinical Studies 2019nCoV-501, 2019nCoV-302, and 2019nCoV-301 (both adult and pediatric) and the initial pediatric vaccination are not included in this submission.
5. FDA Guidance for Industry: Emergency Use Authorization for Vaccines to Prevent COVID-19 (25 May 2021).

#### 2.5.1.3.1 Key Regulatory Interactions

The SARS-CoV-2 rS clinical program was conducted following the Good Clinical Practice (GCP) principles as outlined in ICH E6 (R2). In addition, Novavax developed the program in accordance with the emerging global guidelines for COVID-19 vaccine development, including, but not limited to, those issued by the European Medicines Agency (EMA), Medicines and Healthcare products Regulatory Agency (MHRA), United States (US) Food and Drug Administration (US FDA), and the World Health Organization (WHO).

Global regulators, including EMA, MHRA, Therapeutic Goods Administration (TGA), and US FDA have generally agreed through various scientific advice and presubmission meetings that the clinical development program for the SARS-CoV-2 rS vaccine with Matrix-M adjuvant is acceptable to support applications for emergency, conditional, or provisional use and subsequent full approval. In addition, the MHRA reviewed and approved Clinical Study 2019nCoV-302 for the UK Phase 3 study, as well as all subsequent changes during study conduct prior to implementation. Likewise, the US FDA, as well as the Federal Commission for Protection against Sanitary Risks (COFEPRIS) in Mexico, reviewed Clinical Study 2019nCoV-301 and all subsequent amendments prior to implementation.

Novavax affirms that the accumulated safety and efficacy data summarized herein are sufficient to meet the requirements for initial authorization. Of note, these data meet the key recommendations in the EMA *Considerations on COVID-19 Vaccine Approval* (16 November 2020), US FDA *Guidance for Industry: Emergency Use Authorization for Vaccines to Prevent COVID-19 (May 2021),* and WHO *Considerations for Evaluation of COVID-19 Vaccines (25 November 2020)* as follows:

- Demonstration of ~90% overall vaccine efficacy (VE) in 2 Phase 3 studies (Clinical Studies 2019nCoV-301 and 2019nCoV-302) in the per-protocol analysis sets, exceeding the required threshold of at least 50% with the lower bound of the confidence interval > 30%.
- Nine severe cases of COVID-19 with onset from at least 7 days after second vaccination (eg, Day 28) were reported in the placebo group contrasted with zero in the active treatment group from Clinical Studies 2019nCoV-301 (4 severe cases) and 2019nCoV-302 (5 severe cases). Additionally, 5 severe cases of COVID-19 with onset from at least 7 days after second vaccination (eg, Day 28) were reported in the placebo group contrasted with zero in the active treatment group in Clinical Study 2019nCoV-501. In total, 14 severe cases of COVID-19 were accrued in the placebo group across the 3 efficacy studies in the per-protocol analysis contrasted to zero severe cases in the active treatment group. The case definition, including severe cases, in Clinical Studies 2019nCoV-501 (South Africa), 2019nCoV-302 (UK), and 2019nCoV-301 (US/Mexico) are all the same.
- Safety database in approximately 30,000 participants exposed to the SARS-CoV-2 rS vaccine with Matrix-M adjuvant at the dose and regimen intended for authorization across the Phase 1 to Phase 3 clinical studies.

- A median duration of at least 60 days safety follow-up in each of the 2 Phase 3 studies (7,467 participants received NVX-CoV2373 in Clinical Study 2019nCoV-302 and 19,104 participants received NVX-CoV2373 in Clinical Study 2019nCoV-301).
- A robust bioanalytical program to evaluate clinical immunology samples (see Section 2.5.2.2).

## 2.5.2 OVERVIEW OF BIOPHARMACEUTICS

### 2.5.2.1 Product Overview

Table 2.5-2 provides a summary of all SARS-CoV-2 rS drug substance (DS) and DP lots used in Novavax-sponsored clinical studies in support of the initial application. This includes lots used in the initial set of vaccinations (ie, Days 0 and 21 [+ 7 days]) for each clinical study (Clinical Studies 2019nCoV-101 (Part 1 and Part 2), 2019nCoV-501, 2019nCoV-302, and 2019nCoV-301), which correlates with the data presented in the interim reports submitted to date to support an initial dosing regimen in adults ≥ 18 years of age administered on Days 0 and 21 (+ 7 days). In addition, for completeness, Table 2.5-2 provides lots that are currently being used in booster, blinded crossover, and pediatric vaccinations for which data are not available for the initial application and will be filed as appropriate in subsequent amendments or variations.

Briefly, the initial vaccinations for the Phase 1 and Phase 2 clinical studies (Clinical Studies 2019nCoV-101 [Part 1 and Part 2] and 2019nCoV-501), as well as the UK Phase 3 study (Clinical Study 2019nCoV-302) used DS produced at the 50 L scale by Emergent BioSolutions (EBSI) (Baltimore, Maryland, US). The US/Mexico Phase 3 study (Clinical Study 2019nCoV-301) used DS produced at the 2000 L scale by FujiFilm Diosynth Biotechnologies (FDBU) (Research Triangle Park, North Carolina, US).

The DP formulation used in all clinical studies was the same and is the formulation for commercial product: 25 mM sodium phosphate (pH 7.2), 300 mM sodium chloride, and 0.01% polysorbate 80. The majority of clinical studies used SARS-CoV-2 rS antigen and Matrix-M adjuvant co-formulated drug product; with the exception of the Phase 1 (Part 1) portion of Protocol 2019nCoV-101 that used antigen and adjuvant mixed on the day of administration (ie, bedside mixed). The reactogenicity and immunogenicity profile between the Phase 1 (bedside mix) and Phase 2 (co-formulated) portions of Clinical Study 2019nCoV-101 were comparable (see Section 2.5.5 and Section 2.5.6, respectively).

Complete details of manufacturing process development and analytical comparability between clinical trial material and proposed commercial material across relevant DS and DP manufacturing facilities intended for commercialization are provided in Module 3.2.S.2.6 for DS and Module 3.2.P.2.3 for DP.

**Table 2.5-2: Summary of SARS-CoV-2 rS Lots Used in Clinical Trials**

| DP Lot | Phase Study No (Country)[1] | DP Manufacturer /Address | DP DOM | DP Presentation | DS Lot | DS DOM | DS Manufacturer /Address |
|---|---|---|---|---|---|---|---|
| **Initial Vaccination (Days 0 and 21 [+ 7 days])** | | | | | | | |
| 2868-101 | Phase 1<br>2019nCoV-101<br>Part 1 | Emergent BioSolutions<br>Baltimore, MD, US | 29 Apr 2020 | 70 µg/mL antigen (bedside mixing with Matrix-M)<br>0.7 mL single-dose via[6] | M000000008 | 17 Apr 2020 | Emergent Manufacturing Operations, LLC<br>Baltimore, MD, US |
| 2868-102 | Phase 1<br>2019nCoV-101<br>Part 1 | Emergent BioSolutions<br>Baltimore, MD, US | 12 May 2020 | 70 µg/mL antigen (bedside mixing with Matrix-M)[6] | M000000010 | 28 Apr 2020 | Emergent Manufacturing Operations, LLC<br>Baltimore, MD, US |
| 2871-101 | Phase 2<br>2019nCoV-101<br>Part 2 | Emergent BioSolutions<br>Baltimore, MD, US | 17 Jul 2020 | 50 µg/mL antigen /<br>100 µg/mL Matrix-M<br>0.7 mL single-dose vial | 21001673 | 20 Jun 2020 | Emergent Manufacturing Operations, LLC<br>Baltimore, MD, US |
| 2870-101 | Phase 2<br>2019nCoV-101<br>Part 2<br><br>Phase 2<br>2019nCoV-501<br><br>Phase 3<br>2019nCoV-302 | Emergent BioSolutions<br>Baltimore, MD, US | 20 Jul 2020 | 10 µg/mL antigen w/<br>100 µg/mL Matrix-M<br>0.7 mL single-dose vial | 21001673 | 20 Jun 2020 | Emergent Manufacturing Operations, LLC<br>Baltimore, MD, US |
| 2870-102 | Phase 3<br>2019nCoV-302<br><br>Phase 2<br>2019nCoV-501 | Emergent BioSolutions<br>Baltimore, MD, US | 17 Aug 2020 | 10 µg/mL antigen w/<br>100 µg/mL Matrix-M<br>0.7 mL single-dose vial | 21001692 | 04 Jul 2020 | Emergent Manufacturing Operations, LLC<br>Baltimore, MD, US |
| Par 28003 | Phase 3<br>2019nCoV-301 | Par Sterile Products, LLC<br>870 Parkdale Road<br>Rochester, MI<br>48307 US | 12 Nov 2020 | 10 µg/mL antigen w/<br>100 µg/mL Matrix-M<br>6.0 mL multi-dose vial | GR1350007 | 05 Nov 2020 | FujiFilm Diosynth Biotechnologies,<br>Research Triangle Park,<br>NC, US (FDBU) |

**Table 2.5-2: Summary of SARS-CoV-2 rS Lots Used in Clinical Trials**

| DP Lot | Phase<br>Study No<br>(Country)[1] | DP Manufacturer<br>/Address | DP DOM | DP Presentation | DS Lot | DS DOM | DS Manufacturer<br>/Address |
|---|---|---|---|---|---|---|---|
| **Booster or Blinded Crossover Vaccination (Data not available for initial application)** | | | | | | | |
| Par 28003 | Phase 2<br>2019nCoV-101<br>Part 2[2]<br><br>Phase 2<br>2019nCoV-501[3] | Par Sterile<br>Products, LLC<br>870 Parkdale Road<br>Rochester, MI<br>48307 US | 12 Nov 2020 | 10 µg/mL antigen +<br>100 µg/mL Matrix-M<br>6.0 mL multi-dose vial | GR1350007 | 05 Nov 2020 | FujiFilm Diosynth<br>Biotechnologies,<br>Research Triangle Park,<br>NC, US (FDBU) |
| Par 28004 | Phase 3<br>2019nCoV-301[4]<br><br>Phase 3<br>2019nCoV-302[5]<br><br>Phase 2<br>2019nCoV-501[3] | Par Sterile<br>Products, LLC<br>870 Parkdale Road<br>Rochester, MI<br>48307 US | 15 Dec 2020 | 10 µg/mL antigen w/<br>100 µg/mL Matrix-M<br>6.0 mL MDV | GR1350009 | 24 Nov 2020 | FujiFilm Diosynth<br>Biotechnologies,<br>Research Triangle Park,<br>NC, US (FDBU) |

Abbreviations: DOM = date of manufacture; DP = drug product; DS = drug substance.

1. Clinical Study 2019nCoV-101 (Part 1) is being conducted in Australia; Clinical Study 2019nCoV-101 (Part 2) is being conducted in Australia and the United States; Clinical Study 2019nCoV-501 is being conducted in South Africa; Clinical Study 2019nCoV-302 is being conducted in the United Kingdom; Clinical Study 2019nCoV-301 (PREVENT-19) is being conducted in the United States and Mexico.
2. Evaluated in the booster dose at Day 189 in Clinical Study 2019nCoV-101 (Part 2).
3. Evaluated in the blinded crossover portion of Clinical Study 2019nCoV-501.
4. Evaluated in the Adult Main Study blinded crossover and Pediatric Expansion in Clinical Study 2019nCoV-301.
5. Evaluated in the blinded crossover portion of Clinical Study 2019nCoV-302.
6. Matrix-M was from Lot M1-108.

### 2.5.2.2 Clinical Assays

Table 2.5-3 provides a summary of the bioanalytical assays and status (ie, qualification/ validation) used in the SARS-CoV-2 rS clinical development program to date for which corresponding data are provided in the interim reports summarized herein; links to the respective assay reports located in Module 5.3.1.4 are provided.

In general, all assays were considered fit-for-purpose and/or qualified for use during evaluation of samples from the Phase 1 and Phase 2 studies. The assays were validated, where appropriate (ie, SARS-CoV-2 polymerase chain reaction [PCR], anti-S protein binding immunoglobulin G [IgG], hACE2 receptor binding inhibition, and microneutralization), prior to Phase 3 testing. Assay qualification includes, at a minimum, evaluation of precision and linearity, including the assay lower limit of quantitation (LLOQ). Assay validation includes full precision, linearity, LLOQ, specificity, upper limit of quantitation (ULOQ), and robustness. Assay development, qualification, and validation are performed in accordance with the *EMA Guideline on bioanalytical method validation* (21 July 2011) and the *US FDA Guidance for Industry: Bioanalytical Method Validation* (May 2018).

It is noted that the anti-S protein binding IgG, microneutralization, and hACE2 receptor binding inhibition assays described herein were all based on the original Wuhan strain. Assays are being developed for further evaluation of immunogenicity against variant strains (eg, Alpha, Beta, and Delta), and these data may be provided in subsequent reports as available.

**Table 2.5-3: Summary of Bioanalytical Assays Used in Clinical Trials**

| Assay | Bioanalytical Assay Site and Status by Clinical Study [Report] | | | | |
|---|---|---|---|---|---|
| | **Phase 1 2019nCoV-101, Part 1** | **Phase 2 2019nCoV-101, Part 2** | **Phase 2 2019nCoV-501** | **Phase 3 2019nCoV-302** | **Phase 3 2019nCoV-301** |
| **Primary/Secondary Endpoints[1]** | | | | | |
| SARS-CoV-2 PCR | *ThermoFisher TaqPath*<br>360biolabs (Melbourne, AU)<br>Qualified [360bl-VE_NOVA-04_TaqPath_RT-PCR.v01] | *ThermoFisher TaqPath*<br>AU Sites: 360biolabs (Melbourne, AU)<br>Qualified [360bl-VE_NOVA-04_TaqPath_RT-PCR.v01]<br>US Sites: P23 Labs (Little Rock, Arkansas, US)<br>Qualified [EUA Summary: P23 20Oct2020] | *BD MAX™*<br>Central Laboratory Services (Johannesburg, ZA)<br>Validated [SARS-CoV-2 PCR Assay Used in Protocol 2019nCoV-501] | *ThermoFisher TaqPath*<br>Public Health England at 3 locations: Milton Keynes, Alderly Park (Manchester), and Glasgow, UK<br>Validated [SARS-CoV-2 PCR Assay Used in Protocol 2019nCoV-302] | *Abbott RealTime SARS-CoV-2 Assay*<br>University of Washington (Seattle, Washington, US)<br>Validated [Abbott RealTime Package Insert; VIRO_1000-261; VIRO_1000-264; VIRO_1000-277; VIRO_1000-255]<br>Refer to Section 3.2.1.4 of Interim Report for Clinical Study 2019nCoV-301 |

**Table 2.5-3: Summary of Bioanalytical Assays Used in Clinical Trials**

| Assay | Bioanalytical Assay Site and Status by Clinical Study [Report] | | | | |
|---|---|---|---|---|---|
| | **Phase 1 2019nCoV-101, Part 1** | **Phase 2 2019nCoV-101, Part 2** | **Phase 2 2019nCoV-501** | **Phase 3 2019nCoV-302** | **Phase 3 2019nCoV-301** |
| Anti-N Protein | Not applicable | Not applicable | Meso Scale Diagnostics (Rockville, Maryland, US) Validated [VAL0114.013; VAL0114.011][5] | *Roche Elecsys*® PPD Central Lab (Zaventem, BE) Validated [Anti-SARS-CoV-2 Assay Used in Protocol 2019nCoV-302] | *Roche Elecsys*® University of Washington (Seattle, Washington, US) Validated [Roche Elecsys Package Insert; VIRO-1000-281] Refer to Section 3.2.1.5 of Interim Report for Clinical Study 2019nCoV-301 |
| Anti-S Protein Binding IgG ELISA | Novavax Clinical Immunology (Gaithersburg, MD, US) Qualified [QAG_04388] | | Novavax Clinical Immunology (Gaithersburg, Maryland, US) Validated [QAG_04556; QAG_05168] | Novavax Clinical Immunology (Gaithersburg, Maryland, US) Validated [QAG_04556; QAG_05168] | *Data not available for interim report*[2] |
| **Secondary/Exploratory Endpoints**[1] | | | | | |
| Wild-type Neutralization | University of Maryland School of Medicine (Baltimore, Maryland, US) Fit-for purpose [SOP SARS-CoV-2 Microneutralization Assay] | 360biolabs (Melbourne, AU) Qualified [360bl-QR_NOVA-04_MN_v01] | 360biolabs (Melbourne, AU) Validated [360bl-VR_NOVA-05_MN_v02] | | *Data not available for interim report*[3] |
| hACE2 Receptor Binding Inhibition ELISA | Novavax Clinical Immunology (Gaithersburg, Maryland, US) Validated [QAG_04394; QAG_05890; CL_5.3.1.4_002761] | | *Data not available for interim report*[4] | *Data not available for interim report*[4] | *Data not available for interim report*[4] |
| CMI ELISpot | Not performed | Cellular Technology Limited (Shaker Heights, Ohio, US) Validation [P620-06] | Not performed | *Data not available for interim report* | *Data not available for interim report* |
| CMI ICCS | Novavax Discovery (Gaithersburg, Maryland, US) Fit-for-purpose [P_SOP_2432; CL_5.3.4.1_002725] | *Data not available for interim report* | Not performed | *Data not available for interim report* | *Data not available for interim report* |

**Table 2.5-3: Summary of Bioanalytical Assays Used in Clinical Trials**

| Assay | Bioanalytical Assay Site and Status by Clinical Study [Report] | | | | |
|---|---|---|---|---|---|
| | **Phase 1 2019nCoV-101, Part 1** | **Phase 2 2019nCoV-101, Part 2** | **Phase 2 2019nCoV-501** | **Phase 3 2019nCoV-302** | **Phase 3 2019nCoV-301** |
| **Ad Hoc Testing** | | | | | |
| Whole Genome Sequencing (Strain Variants) | Not applicable | Not applicable | VIDA (Soweto, ZA) Fit-for purpose [nCoV-2019 sequencing protocol v3 (LoCost) V.3] KRSIP (Durban, ZA) Fit-for purpose [SNAP SARS-CoV-2 and SARS-CoV-2 Additional Genome Coverage] | Big Data Institute (Oxford, UK) Wellcome Sanger Institute (Hinxton, UK) *SOP/report not available; not validated* | University of Washington (Seattle, Washington, US) [VIRO_1800-3100] *SOP only; not validated* |

Abbreviations: Anti-N = anti-nucleocapsid; AU = Australia; CMI = cell-mediated immunity; ELISA = enzyme-linked immunosorbent assay; ELISpot = enzyme-linked immunospot; hACE2 = human angiotensin-converting enzyme 2; ICCS = intracellular cytokine staining; IgG = immunoglobulin G; PCR = polymerase chain reaction; S = spike; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; UK = United Kingdom; US = United States of America; ZA = South Africa.

1. The secondary/exploratory endpoint status for each assay varies by study.
2. Anti-S Protein Binding IgG ELISA Testing in Clinical Study 2019nCoV-301 will be performed with QAG_04556.
3. Wild-type Neutralization Testing in Clinical Study 2019nCoV-301 will be performed with 360bl-VR_NOVA-05_MN_v02.
4. hACE2 Inhibition ELISA Testing in Clinical Studies 2019nCoV-301, 2019nCoV-302, and 2019nCoV-501 will be performed with QAG_04394.
5. The Validation Report for MSD® Serology Panel Assays is intrinsically and by design a multi-valent assay. Results for all panels were received; however, only the SARS-CoV-2 nucleocapsid was analyzed in Clinical Study 2019nCoV-501.

## 2.5.3 OVERVIEW OF CLINICAL PHARMACOLOGY

Not applicable for vaccines.

# 2.5.4 OVERVIEW OF EFFICACY

## 2.5.4.1 Study Background

The efficacy of NVX-CoV2373, the 5-µg dose of SARS-CoV-2 rS with 50 µg Matrix-M adjuvant, was formally evaluated in Clinical Studies 2019nCoV-501, 2019nCoV-302, and 2019nCoV-301.

- Clinical Study 2019nCoV-501 is a Phase 2a/b, randomized, observer-blinded, placebo-controlled trial evaluating the efficacy, immunogenicity, and safety of NVX-CoV2373, administered on Days 0 and 21 (+ 7 days) as a co-formulation, in 4,164 healthy human immunodeficiency virus (HIV)-negative participants ≥ 18 to ≤ 84 years of age and in 244 medically stable HIV positive participants ≥ 18 to ≤ 64 years of age conducted at multiple sites in South Africa. This study was initiated on 17 August 2020 and completed enrollment on 25 November 2020. The official event-driven analysis of the primary efficacy endpoint captured 44 PCR-confirmed symptomatic COVID-19 cases as of 18 January 2021, and the complete analysis was based on 147 cases as of 23 February 2021. Immunogenicity data (Day 35) and safety data (through 28 days after second vaccination) were captured as of 23 February 2021. During the conduct of this study, the B.1.351 (Beta) variant was predominant in the country and constituted the majority of sequenced SARS-CoV-2 detections. Please reference 2019nCoV-501 Interim Report for an interim report of these data.
- Clinical Study 2019nCoV-302 is a Phase 3, multicenter, randomized, observer-blind, placebo-controlled study evaluating the efficacy, safety, and immunogenicity of NVX-CoV2373, administered on Days 0 and 21 (+ 7 days) as a co-formulation, in 15,139 clinically stable participants ≥ 18 to ≤ 84 years of age at sites of high SARS-CoV-2 activity in the UK. The study was initiated on 28 September 2020 and completed enrollment on 28 November 2020. The interim analysis of the primary efficacy endpoint captured 62 PCR-confirmed symptomatic COVID-19 cases as of 10 January 2021 and the final analysis captured 106 cases as of 29 January 2021. Immunogenicity data (Day 35) and safety data (including at least a 60-day median safety follow-up) were captured as of 23 February 2021. As an exploratory objective, a substudy was conducted in approximately 400 participants who were co-administered a seasonal influenza vaccine at the first vaccination to evaluate the immunogenicity of the influenza and COVID-19 vaccines. During the conduct of this study, the B.1.1.7 (Alpha) variant emerged as the predominant strain in the country. Please reference 2019nCoV-302 Interim Report for the Main Study and 2019nCoV-302 Interim Report Flu Study for the Seasonal Influenza Vaccine Substudy.
- Clinical Study 2019nCoV-301 is a Phase 3, multinational, multicenter, randomized, observer-blinded, placebo-controlled study evaluating the efficacy, safety, and immunogenicity of NVX-CoV2373, administered on Days 0 and 21 (+ 7 days) as a co-formulation, in 29,582 participants ≥ 18 years of age conducted at multiple sites in the US and Mexico. This study was initiated on 27 December 2020 and completed enrollment on 18 February 2021. The final analysis of the primary efficacy endpoint

captured 77 PCR-confirmed symptomatic COVID-19 cases as of 01 June 2021. Safety data (including at least a 60-day median safety follow-up) were captured as of 01 June 2021. During the conduct of this study, several VOC and Variants of Interest (VOI) were predominant in the countries. Please reference 2019nCoV-301 Interim Report for an interim report of these data.

Study populations across Clinical Studies 2019nCoV-501, 2019nCoV-302, and 2019nCoV-301 comprised participants who, by virtue of age, race, ethnicity, or life circumstances were considered at substantial risk of exposure to and infection with SARS-CoV-2. This included participants ≥ 65 years of age and participants < 65 years of age with co-morbidities (ie, obesity [body mass index (BMI) > 30 kg/m$^2$], chronic kidney or lung disease, cardiovascular disease, type 2 diabetes mellitus, and HIV), who were at higher risk of complications due to COVID-19. Participants were also considered at high risk if their living or working conditions involved known frequent exposure to SARS-CoV-2 or to densely populated circumstances (factory or meat packing plants, essential retail workers, etc). Demographic and baseline characteristics of the 3 efficacy studies can be found in Table 16 of the 2019nCoV-501 Interim Report, Table 14 of the 2019nCoV-302 Interim Report, and Table 11 of the 2019nCoV-301 Interim Report. Demographic and baseline characteristics were generally well balanced across the 2 treatment groups in each study.

The efficacy objectives and endpoints of the studies can be found in Section 2 of the 2019nCoV-501 Interim Report, Section 2 of the 2019nCoV-302 Interim Report, and Section 2 of the 2019nCoV-301 Interim Report, with the primary objectives/endpoints listed in Table 2.5-4. The primary endpoints of the 2 pivotal Phase 3 studies (Clinical Studies 2019nCoV-302 and 2019nCoV-301), in conjunction with their respective statistical analysis, were designed in collaboration with regulatory agencies in consideration of regulatory guidelines (see Section 2.5.1.3.1), to enable emergency use authorization (EUA) and associated regulatory pathways for early approval, as well as ultimately full approval. Statistical methodology for each of the clinical studies can be found in the respective statistical analysis plans included in each of the interim reports.

The analysis sets for the primary efficacy endpoint in each of the 3 efficacy studies is as follows, with the exception that the second Per-Protocol Efficacy (PP-EFF) Analysis Set was not used for Clinical Study 2019nCoV-302 due to lack of baseline seropositivity:

- The **PP-EFF Analysis Set** included baseline seronegative participants who received both doses of trial vaccine (SARS-CoV-2 rS with Matrix-M adjuvant or placebo) and had no major protocol deviations affecting the primary efficacy outcome as assessed by the sponsor prior to unblinding. All analyses of the PP-EFF population excluded any illness episodes with positive SARS-CoV-2 by any validated PCR and/or serum antibody (anti-nucleocapsid [anti-N] or anti-S) occurring before 7 days after the second vaccine dose (eg, Day 28).
- A second **PP-EFF-2 Analysis Set** was defined to allow for evaluation of the impact of the baseline serostatus analysis on 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.

**Table 2.5-4: Summary of Primary Efficacy Objectives and Endpoints Across the Efficacy Studies of NVX-CoV2373**

| Primary Efficacy | Clinical Study 2019nCoV-501 | Clinical Study 2019nCoV-302 | Clinical Study 2019nCoV-301 |
|---|---|---|---|
| Objective | To evaluate the efficacy of NVX-CoV2373 compared to placebo on the occurrence of **symptomatic mild, moderate, or severe** confirmed COVID-19 as demonstrated by qualitative PCR in serologically naïve (to SARS-CoV-2) healthy HIV-negative and medically stable HIV-positive adult participants (analyzed as an **overall** population; initial vaccination period). | To demonstrate the efficacy of NVX-CoV2373 in the prevention of virologically confirmed (by PCR to SARS-CoV-2), **symptomatic COVID-19**, when given as a two-dose vaccination regimen, as compared to placebo, in serologically negative (to SARS-CoV-2) adults. | To evaluate the efficacy of a two-dose regimen of NVX-CoV2373 compared to placebo against 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. |
| Endpoint | **(+) PCR-confirmed SARS-CoV-2 illness with symptomatic mild, moderate, or severe** COVID-19 in serologically naïve (to SARS-CoV-2) healthy HIV-negative and medically stable HIV-positive adult participants, **analyzed overall**, with an LBCI of > 0, from 7 days after the second vaccine dose (eg, Day 28) until the endpoint-driven efficacy analysis is triggered by the occurrence of a prespecified number of blinded endpoints across the 2 trial vaccine arms and/or at prespecified time points during the initial vaccination period. | First occurrence of **virologically confirmed (by PCR to SARS-CoV-2), symptomatic mild, moderate, or severe** COVID-19 with onset from at least 7 days after second study vaccination (eg, Day 28) in the initial set of vaccinations in serologically negative (to SARS-CoV-2) adult participants at baseline until the endpoint-driven efficacy analysis is triggered by the occurrence of a prespecified number of blinded endpoints. | First episode of **PCR-positive mild, moderate, or severe** COVID-19. |

Abbreviations: (+) = positive; COVID-19 = coronavirus disease 2019; HIV = human immunodeficiency virus; LBCI = lower bound confidence interval; NVX-CoV2373 = 5 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant; PCR = polymerase chain reaction; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine; VE = vaccine efficacy.

Both the objectives, endpoints, and COVID-19 endpoint and severity definitions were similar across the efficacy studies and focused on PCR-confirmed symptomatic mild, moderate, or severe COVID-19. Efficacy assessments, including symptoms suggestive of COVID-19 and COVID-19 endpoint and severity definitions, can be found in Section 3.2.1 of the 2019nCoV-501 Interim Report, Section 3.2.1.2 of the 2019nCoV-302 Interim Report, and Section 2 (under the primary efficacy endpoint) and Section 3.2.1 of the 2019nCoV-301 Interim Report).

Key secondary efficacy endpoints across the 3 studies included PCR-confirmed symptomatic mild, moderate, or severe COVID-19 in HIV-negative and HIV-positive adult participants, analyzed separately (Clinical Study 2019nCoV-501); PCR-confirmed symptomatic moderate or severe COVID-19 (Clinical Study 2019nCoV-302); and PCR-confirmed mild, moderate, or severe COVID-19 shown by gene sequencing to represent either a variant not considered as a VOC/VOI or a variant considered as a VOC/VOI according to Centers for Disease Control and Prevention (CDC) classification [CDC 2021] as of 01 June 2021.

For Clinical Study 2019nCoV-301, potentially severe cases of symptomatic PCR-positive COVID-19 were reviewed by an external Independent Endpoint Review Committee (ERC). The ERC consisted of physicians who have clinical and research experience (eg, medical review and/or clinical study experience) in infectious disease. Potentially severe cases included COVID-19 reported as serious adverse events (SAEs), programmatically identified endpoints consisting of at least 1 pulse oximeter reading ≤ 93%, and episodes identified as severe on the Endpoint Assessment electronic case report form (eCRF) (see Section 3.3.3.1 in the 2019nCoV-301 Interim Report for details). Determination of mild and moderate severity categories was done by the investigators or sponsor.

For Clinical Studies 2019nCoV-501 and 2019nCoV-302, COVID-19 severity determination was done via programming algorithms based on the endpoint definitions in the respective studies.

### 2.5.4.2 Study Results

The results of the primary and key secondary efficacy endpoints for Clinical Studies 2019nCoV-501, 2019nCoV-302, and 2019nCoV-301 are presented in Table 2.5-5, Table 2.5-6, and Table 2.5-7, respectively. Of note, there was a total of 14 cases of severe COVID-19 with an onset of at least 7 days after second vaccination (eg, Day 28) across the 3 efficacy studies (5 in Clinical Study 2019nCoV-501, 5 in Clinical Study 2019nCoV-302, and 4 in Clinical Study 2019nCoV-301), all of which occurred in the placebo group.

**Table 2.5-5: Vaccine Efficacies for the Primary and Key Secondary Efficacy Endpoints in Clinical Study 2019nCoV-501**

| Participant Population/ SARS-CoV-2 Strain/Variant | No. of Cases | NVX-CoV2373 | | Placebo | | VE (95% CI)[2] | Interim Report Cross-Reference |
|---|---|---|---|---|---|---|---|
| | | n/N (%)[1] | (95% CI) | n/N (%)[1] | (95% CI) | | |
| **Primary efficacy endpoint (Official Event-Driven Analysis) for PCR-confirmed mild, moderate, or severe COVID-19 with onset from 7 days after second vaccination (eg, Day 28) in participants who were seronegative to SARS-CoV-2 at baseline (PP-EFF Analysis Set), analyzed overall** | | | | | | | |
| All: Any strain/variant | 44 | 15/1357 (1.11) | 0.6, 1.8 | 29/1327 (2.19) | 1.5, 3.1 | 49.4% (6.1, 72.8)[3,4] | Table 17 |
| **Post-hoc analyses of the primary efficacy endpoint (Official Event-Driven Analysis based on PP-EFF Analysis Set), analyzed overall** | | | | | | | |
| All: B.1.351 (Beta) variant | 38 | 14/1357 (1.03) | 0.6, 1.7 | 24/1327 (1.81) | 1.2, 2.7 | 43.0% (-9.8, 70.4)[4] | Table 18 |
| HIV-negative: B.1.351 (Beta) variant | 33 | 11/1281 (0.86) | 0.4, 1.5 | 22/1255 (1.75) | 1.1, 2.6 | 51.0% (-0.6, 76.1)[4] | Table 19 |
| **Primary efficacy endpoint (Complete Analysis) for PCR-confirmed mild, moderate, or severe COVID-19 with onset from 7 days after second vaccination (eg, Day 28) in participants who were seronegative to SARS-CoV-2 at baseline (PP-EFF Analysis Set), analyzed overall** | | | | | | | |
| All: Any strain/variant | 147 | 51/1408 (3.62) | 2.7, 4.7 | 96/1362 (7.05) | 5.7, 8.5 | 48.6% (28.4, 63.1)[3,4] | Table 20 |
| **Key secondary efficacy endpoint (Complete Analysis) for PCR-confirmed mild, moderate, or severe COVID-19 with onset from 7 days after second vaccination (eg, Day 28) in participants who were seronegative to SARS-CoV-2 at baseline (PP-EFF Analysis Set), analyzed separately** | | | | | | | |
| HIV-negative: Any strain/variant | 130 | 41/1331 (3.08) | 2.2, 4.2 | 89/1289 (6.91) | 5.6, 8.4 | 55.4% (35.9, 68.9)[4] | Table 20 |
| HIV-positive: Any strain/variant | 17 | 10/77 (13.0) | 6.4, 22.6 | 7/73 (9.59) | 3.94, 18.76 | -35.4% (-236.9, 45.6)[4] | Table 20 |

Abbreviations: CI = confidence interval; COVID-19 = coronavirus disease 2019; HIV = human immunodeficiency virus; IgG = immunoglobulin G; LBCI = lower bound confidence interval; n = number of participants with NAAT-confirmed COVID-19; N = number of participants; NAAT = nucleic acid amplification test; NVX-CoV2373 = 5 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant; PCR = 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.

1. Percentage of participants with COVID-19 calculated as n/N × 100.
2. The 95% CI for PCR-confirmed COVID-19 infection was calculated using the exact Clopper-Pearson method. Participants were counted as a COVID-19 case only for the first PCR-positive illness episode. Once that case had been determined, it was further classified to a severity level.
3. Met primary efficacy endpoint criterion for success with a LBCI > 0%.
4. Based on log-linear model of PCR-confirmed COVID-19 infection incidence rate using Poisson regression with treatment group as fixed effects and robust error variance, where VE = 100 × (1 – relative risk) [Zou 2004].

**Table 2.5-6: Vaccine Efficacies for the Primary and Key Secondary Efficacy Endpoints in Clinical Study 2019nCoV-302**

| Participant Population SARS-CoV-2 Strain/Variant | No. of Cases | NVX-CoV2373 | | Placebo | | VE (95% CI) | Interim Report Cross-Reference |
|---|---|---|---|---|---|---|---|
| | | n/N (%)[1] | Mean Disease Incidence Rate[2] (95% CI) | n/N (%)[1] | Mean Disease Incidence Rate[2] (95% CI) | | |
| **Primary efficacy endpoint (Interim Analysis) for PCR-confirmed mild, moderate, or severe COVID-19 with onset from 7 days after second vaccination (eg, Day 28) in participants who were seronegative to SARS-CoV-2 at baseline (PP-EFF Analysis Set)** | | | | | | | |
| All: Any strain/variant | 62 | 6/7009 (< 0.1) | 5.06 (1.94, 13.18) | 56/7027 (0.8) | 47.30 (28.72, 77.88) | 89.3% (75.2, 95.4)[3,4] | Table 16 |
| **Post-hoc analyses of the primary efficacy endpoint (Interim Analysis based on PP-EFF Analysis Set)** | | | | | | | |
| All: B.1.1.7 (Alpha) variant[5] | 32 | 4/7008 (< 0.1) | --- | 28/7022 (0.4) | --- | 85.7% (59.2, 95.0)[3] | Table 17 |
| All: Non-B.1.1.7 (Alpha) variant[6] | 24 | 1/7008 (< 0.1) | --- | 23/7022 (0.3) | --- | 95.6% (67.7, 99.4)[3] | Table 17 |
| **Primary efficacy endpoint (Final Analysis) for PCR-confirmed mild, moderate, or severe COVID-19 with onset from 7 days after second vaccination (eg, Day 28) in participants who were seronegative to SARS-CoV-2 at baseline (PP-EFF Analysis Set)** | | | | | | | |
| All: Any strain/variant | 106 | 10/7020 (0.1) | 6.53 (3.32, 12.85) | 96/7019 (1.4) | 63.43 (45.19, 89.03) | 89.7% (80.2, 94.6)[3,4] | Table 18 |
| **Post-hoc analysis of the primary efficacy endpoint (Final Analysis) for PCR-confirmed mild, moderate, or severe COVID-19 with onset from 7 days after second vaccination (eg, Day 28) in participants who were seronegative to SARS-CoV-2 at baseline (PP-EFF Analysis Set)** | | | | | | | |
| All: B.1.1.7 (Alpha) variant[5] | 66 | 8/7020 (0.1) | 4.94 (2.33, 10.48) | 58/7019 (0.8) | 36.11 (23.15, 56.32) | 86.3% (71.3, 93.5)[3] | Table 19 |
| All: Non-B.1.1.7 (Alpha) variant[6] | 29 | 1/7020 (< 0.1) | 0.43 (0.05, 3.79) | 28/7019 (0.4) | 12.15 (4.23, 34.92) | 96.4% (73.8, 99.5)[3] | Table 19 |
| **Subgroup analyses of the primary efficacy endpoint (Final Analysis) for PCR-confirmed mild, moderate, or severe COVID-19 with onset from 7 days after second vaccination (eg, Day 28) in participants who were seronegative to SARS-CoV-2 at baseline (PP-EFF Analysis Set)** | | | | | | | |
| Participants 18 to 64 years of age | 96 | 9/5067 (0.2) | 12.30 (6.36, 23.78) | 87/5062 (1.7) | 120.22 (94.87, 152.35) | 89.8% (79.7, 94.9)[3] | Table 20 |
| Participants 65 to 84 years of age | 10 | 1 (0.10)[3] | --- | 9 (0.90)[3] | --- | 88.9% (20.2, 99.7)[5] | Table 20 |
| Participants of White race | 93 | 8/6625 (0.1) | 5.74 (2.70, 12.22) | 85/6635 (1.3) | 61.75 (43.33, 87.98) | 90.7% (80.8, 95.5)[3] | Table 20 |
| Participants of non-White race[7] | 8 | 2 (0.25)[8] | --- | 6 (0.75)[8] | --- | 66.3% (-88.4, 96.7)[8] | Table 20 |
| Participants of non-White race[9] | 10 | 2 (0.20)[8] | --- | 8 (0.80)[8] | --- | 75.7% (-21.6, 97.5)[8] | Table 20 |
| Participants with co-morbidities[10] | 36 | 3/3117 (< 0.1) | 4.70 (1.44, 15.36) | 33/3143 (1.0) | 51.77 (29.48, 90.92) | 90.9% (70.4, 97.2)[3] | Table 20 |
| Participants without co-morbidities | 70 | 7/3903 (0.2) | 7.86 (3.45, 17.92) | 63/3876 (1.6) | 72.02 (46.36, 111.90) | 89.1% (76.2, 95.0)[3] | Table 20 |

**Table 2.5-6: Vaccine Efficacies for the Primary and Key Secondary Efficacy Endpoints in Clinical Study 2019nCoV-302**

| Participant Population SARS-CoV-2 Strain/Variant | No. of Cases | NVX-CoV2373 | | Placebo | | VE (95% CI) | Interim Report Cross-Reference |
|---|---|---|---|---|---|---|---|
| | | n/N (%)[1] | Mean Disease Incidence Rate[2] (95% CI) | n/N (%)[1] | Mean Disease Incidence Rate[2] (95% CI) | | |
| **Key secondary efficacy endpoint (Final Analysis) for PCR-confirmed moderate or severe COVID-19 with onset from 7 days after second vaccination (eg, Day 28) in participants who were seronegative to SARS-CoV-2 at baseline (PP-EFF Analysis Set)** | | | | | | | |
| All: Any strain/variant | 77 | 9/7020 (0.1) | 5.43 (2.54, 11.63) | 68/7019 (1.0) | 41.38 (26.88, 63.72) | 86.9% (73.7, 93.5)[3] | Table 24 |
| **Post-hoc analysis of the key efficacy endpoint (Final Analysis) for PCR-confirmed moderate or severe COVID-19 with onset from 7 days after second vaccination (eg, Day 28) in participants who were seronegative to SARS-CoV-2 at baseline (PP-EFF Analysis Set)** | | | | | | | |
| All: B.1.1.7 (Alpha) variant[5] | 50 | 7/7020 (< 0.1) | 4.48 (1.97, 10.16) | 43/7019 (0.6) | 27.66 (16.84, 45.44) | 83.8% (64.0, 92.7)[3] | Table 25 |
| All: Non-B.1.1.7 (Alpha) variant[6] | 20 | 1 (0.05)[8] | --- | 19 (0.95)[8] | --- | 94.8% (67.1, 99.9)[8] | Table 25 |
| **Exploratory efficacy endpoint (Final Analysis) for PCR-confirmed mild, moderate, or severe COVID-19 with onset from 7 days after second vaccination (eg, Day 28) in participants who were seronegative to SARS-CoV-2 at baseline (PP-EFF Analysis Set) in the Seasonal Influenza Vaccine Substudy** | | | | | | | |
| All participants: B.1.1.7 (Alpha) variant[5] | 10 | 2 (1.0) | 70.37 (9.46, 523.51) | 8 (4.1) | 279.58 (109.89, 711.26) | 74.8% (-19.7, 94.7)[3] | Table 5[11] |
| Participants 18 to 64 years of age: B.1.1.7 (Alpha) variant[5] | 9 | 1 (0.6) | 29.74 (4.19, 211.21) | 8 (4.4) | 238.01 (118.25, 479.05) | 87.5% (-0.2, 98.4)[3] | Table 6[11] |

Abbreviations: BMI = body mass index; CI = confidence interval; COVID-19 = coronavirus disease 2019; LBCI = lower bound confidence interval; n = number of participants with confirmed COVID-19; N = number of participants; NVX-CoV2373 = 5 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant; PCR = 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; VE = vaccine efficacy.

1. Percentage of participants with COVID-19 calculated as n/N × 100.
2. Mean disease incidence rate per year in 1000 people.
3. Based on log-linear model of PCR-confirmed COVID-19 infection incidence rate using Poisson regression with treatment group as fixed effects and robust error variance, where VE = 100 × (1 – relative risk) (Zou 2004).
4. Met primary efficacy endpoint criterion for success with a LBCI > 30%.
5. Based on genomic sequencing for B.1.1.7 (Alpha) variant.
6. No additional genomic sequencing was performed on samples tested negative for B.1.1.7 (Alpha) variant; therefore, these samples were designated as non-B.1.1.7 (Alpha) variants.
7. Includes ethnic minorities.
8. The Clopper-Pearson model replaced the log-linear model using the modified Poisson regression because few events were observed in at least 1 of the study vaccine groups (or at least 1 stratum) and Poisson regression analysis failed to converge. The 95% CIs calculated using the Clopper-Pearson exact binomial method adjusted for the total surveillance time. Event rates were documented as proportions of the total number of events.
9. Includes ethnic minorities and multiple race categories.
10. Comorbid participants were those who had at least 1 of the comorbid conditions reported as a medical history or had a screening BMI > 30 kg/m$^2$.
11. From the 2019nCoV-302 Interim Report Flu Substudy.

**Table 2.5-7: Vaccine Efficacies for the Primary and Key Secondary Efficacy Endpoints in Clinical Study 2019nCoV-301**

| Participant Population/ SARS-CoV-2 Strain/Variant | No. of Cases | NVX-CoV2373 | | Placebo | | VE (95% CI) | Interim Report Cross-Reference |
|---|---|---|---|---|---|---|---|
| | | n/N (%)[1] | Mean Disease Incidence Rate[2] (95% CI) | n/N (%)[1] | Mean Disease Incidence Rate[2] (95% CI) | | |
| **Primary efficacy endpoint (Final Analysis) for PCR-confirmed mild, moderate, or severe COVID-19 with onset from 7 days after second vaccination (eg, Day 28) in participants who were seronegative to SARS-CoV-2 at baseline (PP-EFF Analysis Set)** | | | | | | | |
| All participants: Any strain/variant | 77 | 14/17312 (0.1) | 3.26 (1.55, 6.89) | 63/8140 (0.8) | 34.01 (20.70, 55.87) | 90.40% (82.88, 94.62)[3,4] | Table 13 |
| **Subgroup analyses of the primary efficacy endpoint (Final Analysis) for PCR-confirmed mild, moderate, or severe COVID-19 with onset from 7 days after second vaccination (eg, Day 28) in participants who were seronegative to SARS-CoV-2 at baseline (PP-EFF Analysis Set)** | | | | | | | |
| Participants 18 to 64 years of age | 73 | 12/15264 (0.1) | 4.60 (2.61, 8.10) | 61/7194 (0.8) | 54.11 (42.10, 69.56) | 91.50% (84.21, 95.42)[3] | Table 14 |
| Male participants | 28 | 5/9050 (0.1) | 3.22 (1.34, 7.74) | 23/4131 (0.6) | 35.35 (23.49, 53.19) | 90.89% (76.03, 96.54)[3] | Table 14 |
| Female participants | 49 | 9/8262 (0.1) | 6.40 (3.33, 12.30) | 40/4009 (1.0) | 63.89 (46.85, 87.12) | 89.99% (79.36, 95.14)[3] | Table 14 |
| White participants | 60 | 12/13140 (0.1) | 5.45 (3.10, 9.60) | 48/6184 (0.8) | 51.31 (38.66, 68.08) | 89.37% (79.99, 94.35)[3] | Table 14 |
| Non-White participants | 16 | 2/4068 (< 0.1) | 2.70 (0.67, 10.79) | 14/1911 (0.7) | 41.92 (24.82, 70.82) | 93.57% (71.68, 98.54)[3] | Table 14 |
| Black or African American participants | 7 | 0/1893 (0.0) | 0.00 (0.00, 11.13) | 7/905 (0.8) | 45.58 (18.32, 93.91) | 100.00% (67.86, 100.00)[5] | Table 14 |
| Hispanic or Latino participants | 19 | 8/3733 (0.2) | 11.76 (5.88, 23.52) | 11/1751 (0.6) | 35.96 (19.91, 64.95) | 67.28% (18.65, 86.84)[3] | Table 14 |
| Not Hispanic or Latino participants | 58 | 6/13538 (< 0.1) | 2.64 (1.19, 5.88) | 52/6379 (0.8) | 53.66 (40.88, 70.42) | 95.08% (88.54, 97.89)[3] | Table 14 |
| US participants | 76 | 14/16294 (0.1) | 5.12 (3.03, 8.65) | 62/7638 (0.8) | 53.13 (41.42, 68.15) | 90.36% (82.78, 94.60)[3] | Table 14 |
| Participants with co-morbidities[6] | 41 | 7/8109 (0.1) | 3.09 (1.07, 8.96) | 34/3910 (0.9) | 33.46 (16.61, 67.37) | 90.76% (79.16, 95.90)[3] | Table 14 |
| Participants without co-morbidities | 36 | 7/9203 (0.1) | 3.52 (1.24, 10.03) | 29/4230 (0.7) | 35.01 (17.30, 70.86) | 89.94% (77.05, 95.59)[3] | Table 14 |

**Table 2.5-7: Vaccine Efficacies for the Primary and Key Secondary Efficacy Endpoints in Clinical Study 2019nCoV-301**

| Participant Population/ SARS-CoV-2 Strain/Variant | No. of Cases | NVX-CoV2373 | | Placebo | | VE (95% CI) | Interim Report Cross-Reference |
|---|---|---|---|---|---|---|---|
| | | n/N (%)[1] | Mean Disease Incidence Rate[2] (95% CI) | n/N (%)[1] | Mean Disease Incidence Rate[2] (95% CI) | | |
| High-risk participants[7] | 75 | 13/16493 (0.1) | 3.15 (1.46, 6.78) | 62/7737 (0.8) | 34.86 (21.23, 57.22) | 90.96% (83.57, 95.03)[3] | Table 14 |
| **Key secondary efficacy endpoint (Final Analysis) for PCR-confirmed mild, moderate, or severe COVID-19 due to a SARS-CoV-2 variant not considered as a VOC/VOI with onset from 7 days after second vaccination (eg, Day 28) in participants who were seronegative to SARS-CoV-2 at baseline (PP-EFF Analysis Set)** | | | | | | | |
| All participants | 10 | 0/17312 (0.0) | 0.00 (< 0.01, 1.25) | 10/8140 (0.1) | 7.83 (3.76, 14.40) | 100.00% (80.75, 100.00)[5] | Table 15 |
| **Key secondary efficacy endpoint (Final Analysis) for PCR-confirmed mild, moderate, or severe COVID-19 due to a SARS-CoV-2 variant considered as a VOC/VOI with onset from 7 days after second vaccination (eg, Day 28) in participants who were seronegative to SARS-CoV-2 at baseline (PP-EFF Analysis Set)** | | | | | | | |
| All participants | 44 | 6/17312 (< 0.1) | 1.31 (0.42, 4.06) | 38/8140 (0.5) | 19.26 (9.62, 38.56) | 93.18% (83.87, 97.12)[3] | Table 18 |
| All participants: B.1.1.7 (Alpha) variant (post-hoc analysis) | 31 | 4/17312 (< 0.1) | 1.35 (0.51, 3.60) | 27/8140 (0.3) | 21.15 (14.50, 30.83) | 93.61% (81.73, 97.76) | Table 20 |

Abbreviations: BMI = body mass index; CI = confidence interval; COVID-19 = coronavirus disease 2019; LBCI = lower bound confidence interval; n = number of participants with confirmed COVID-19; N = number of participants; NVX-CoV2373 = 5 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant; PCR = 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; VE = vaccine efficacy.

1. Percentage of participants with COVID-19 calculated as n/N × 100.
2. Mean disease incidence rate per year in 1000 people.
3. Based on log-linear model of PCR-confirmed COVID-19 infection incidence rate using Poisson regression with treatment group as fixed effects and robust error variance, where VE = 100 × (1 – relative risk) (Zou 2004).
4. Met primary efficacy endpoint criterion for success with a LBCI > 30%.
5. 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 was estimated with 1 – ratio of incidence rates using the exact method conditional on the total number of cases..
6. Comorbidities: Obesity (BMI ≥ 30 kg/m$^2$), chronic kidney disease, chronic lung disease, cardiovascular disease, diabetes mellitus type 2.
7. 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.

### 2.5.4.3 Efficacy Conclusions

Across the Phase 2a/b and 2 pivotal Phase 3 efficacy studies, a two-dose regimen of NVX-CoV2373 (5 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant), administered at least 21 days (+ 7 days) apart, met the prespecified study success criterion of their respective studies versus placebo in preventing PCR-confirmed symptomatic mild, moderate, or severe COVID-19 with onset from at least 7 days after second vaccination (eg, Day 28) in serologically negative (to SARS-CoV-2) adult participants ≥ 18 years of age. This includes data from 2 pivotal Phase 3 efficacy trials independently demonstrating ~90% efficacy against COVID-19 with a lower bound confidence interval (LBCI) > 30%, as well as 100% efficacy against severe disease.

- In the Clinical Study 2019nCoV-501 in South Africa, the primary efficacy endpoint was achieved with VEs of 49.4% (95% confidence interval [CI]: 6.1, 72.8) with an LBCI > 0% (official event-driven analysis) and 48.6% (95% CI: 28.4, 63.1) with an LBCI > 0% (complete analysis) in both HIV-negative and HIV-positive participants, during a period in which the B.1.351 (Beta) variant was predominant in the country. The key secondary efficacy endpoint was achieved in HIV-negative participants with a VE of 55.4% (95% CI: 35.9, 68.9).
- In Clinical Study 2019nCoV-302 in the UK, the primary efficacy endpoint was achieved with VEs of 89.3% (95% CI: 75.2, 95.4) with an alpha adjusted LBCI > 30% (interim analysis) and 89.7% (95% CI: 80.2, 94.6) with an LBCI > 30% (final analysis), during a period in which the B.1.1.7 (Alpha) variant was predominant in the country. The key second efficacy endpoint of moderate or severe COVID-19 was also achieved with a VE of 86.9% (95% CI: 73.7, 93.5).
- In Clinical Study 2019nCoV-301 in the US and Mexico, The primary efficacy endpoint was achieved with a VE of 90.40% (95% CI: 82.88, 94.62) with an LBCI > 30%, during a period in which variants non-identical with the Wuhan-Hu-1 prototype strain and considered VOC/VOI were predominant in the countries. Key secondary efficacy endpoints showed VEs of 100.00% (95% CI: 80.75, 100.00) for SARS-CoV-2 variants not considered a VOC/VOI and 93.18% (95% CI: 83.87, 97.12) for SARS-CoV-2 variants considered a VOC/VOI.
- There was a total of 14 cases of severe COVID-19 with an onset of at least 7 days after second vaccination (eg, Day 28) across the 3 efficacy studies (5 in Clinical Study 2019nCoV-501, 5 in Clinical Study 2019nCoV-302, and 4 in Clinical Study 2019nCoV-301), all of which occurred in the placebo group.

## 2.5.5 OVERVIEW OF IMMUNOGENICITY

### 2.5.5.1 Study Background

Immunogenicity was evaluated by primary and secondary immunogenicity endpoints in Clinical Studies 2019nCoV-101 (Part 1) and 2019nCoV-101 (Part 2) and by secondary immunogenicity endpoints in Clinical Studies 2019nCoV-501 and 2019nCoV-302. In Clinical Study 2019nCoV-302, a seasonal influenza vaccine substudy was also conducted to assess the possible impact of NVX-CoV2373 on the immunogenicity of the co-administered influenza vaccine, as well as the impact of influenza vaccines on the immunogenicity of the COVID-19 vaccine. Immunogenicity data are not yet available from Clinical Study 2019nCoV-301.

- Part 1 of Clinical Study 2019nCoV-101 is a Phase 1, first-in-human, randomized, observer-blinded, placebo-controlled trial evaluating the safety and immunogenicity of 5-µg and 25-µg doses of SARS-CoV-2 rS with or without 50 µg Matrix-M adjuvant in 131 healthy adult participants ≥ 18 to ≤ 59 years of age conducted in Australia. The study was initiated on 25 May 2020 and completed enrollment on 06 June 2020. Safety and immunogenicity data through Day 189 were captured as of 10 December 2020. Please reference 2019nCoV-101 (Part 1) Interim Report for an interim report of these data.
- Part 2 of Clinical Study 2019nCoV-101 is a Phase 2 randomized, placebo-controlled, observer-blinded study evaluating the safety and immunogenicity of 5-µg and 25-µg doses of SARS-CoV-2 rS with 50 µg Matrix-M adjuvant in 1,283 healthy adult participants ≥ 18 to ≤ 84 years of age conducted in in Australia and the US. The study was initiated on 24 August 2020 and completed enrollment on 25 September 2020. Safety and immunogenicity data through Day 35 were captured as of 09 December 2020. Please reference 2019nCoV-101 (Part 2) Interim Report for an interim report of these data.
- Clinical Studies 2019nCoV-501 and 2019nCoV-302 (including the exploratory Seasonal Influenza Vaccine Substudy) are described in Section 2.5.4.1.

The immunogenicity objectives and endpoints of the studies can be found in Section 2 of the 2019nCoV-101 (Part 1) Interim Report, Section 2 of the 2019nCoV-101 (Part 2) Interim Report, Section 2 of the 2019nCoV-501 Interim Report, and Section 2 of the 2019nCoV-302 Interim Report. Immunogenicity endpoints included serum anti-S protein IgG and serum ACE2 receptor binding inhibition specific to SARS-CoV-2 rS protein antigen; neutralizing antibodies specific for SARS-CoV-2 wild-type virus; and cell-mediated immune (CMI) response assessed by polyfunctional $CD4^+$ T cells to differentiate pathways of either Type 1 T helper (Th1) or Type 2 T helper (Th2) predominance. The assays used and laboratories performing these assessments are described in Table 2.5-3. Available immunogenicity assessments included in the interim reports are as follows:

- In the 2019nCoV-101 (Part 1) Interim Report, immunogenicity (anti-S protein IgG, hACE2 receptor inhibition, neutralizing antibody, and/or CMI) was assessed on Days 0, 7, 21, 28, 35, 49, 105, and 189.
- In the 2019nCoV-101 (Part 2) Interim Report, immunogenicity (anti-S protein IgG, hACE2 receptor inhibition, neutralizing antibody, and/or CMI) was assessed on Days 0, 21, and 35.
- In the 2019nCoV-501 Interim Report, immunogenicity (anti-S protein IgG and neutralizing antibody) was assessed on Days 0, 21, and 35.
- In the 2019nCoV-302 Interim Report, immunogenicity for the main study (anti-S protein IgG and neutralizing antibody) was assessed on Days 0, 21, and 35.
- In the 2019nCoV-302 Interim Report Flu Substudy, immunogenicity (hemagglutination inhibition [HAI] assay and/or anti-S protein IgG) was assessed on Days 0, 21, and 35. For the HAI assay, 2 seasonal influenza vaccines were administered: an unadjuvanted quadrivalent influenza vaccine (Flucelvax®, Seqirus; also referred to as QIVc) was given to those 18 to 64 years of age and an adjuvanted trivalent influenza vaccine (Fluad®, Seqirus; also referred to as aTIV) was given to those ≥ 65 years of age, per UK guidance. The WHO recommendations for the 2020-2021 Northern Hemisphere influenza season for quadrivalent and trivalent vaccines [WHO 2020b] were A/Nebraska/14/ 2019 (an A/Hawaii/70/2019 (H1N1) pdm09-like virus), A/Delaware/39/2019 (an A/HongKong/ 45/2019 (H3N2)-like virus), B/Darwin/7/2019 (a B/Washington/02/2019-like virus), and B/Singapore/ INFTT-16-0610/2016 (a B/Phuket/ 3073/2013-like virus) for QIVc (Flucelvax) and A/Victoria/2454/2019 IVR-207 (an A/Guangdong-Maonan/ SWL1536/2019 (H1N1) pdm09-like virus, A/HongKong/2671/2019 IVR-208 (an A/HongKong/ 2671/2019 (H3N2)-like virus), and B/Victoria/705/2018 BVR-11 (a B/Washington/02/ 2019-like virus) for aTIV (Fluad).

### 2.5.5.2 Study Results

Key immunogenicity results across the SARS-CoV-2 rS clinical development program are summarized in Table 2.5-8. In the first-in-human Clinical Study 2019nCoV-101 (Part 1), a two-dose regimen of 5 µg or 25 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant administered 21 days (+ 7 days) apart as a bedside mixture of each component induced robust immune responses that were markedly higher than those from either a one-dose 25 µg adjuvanted regimen, a two-dose 25 µg unadjuvanted regimen, or placebo in participants 18 to 59 years of age. In Part 2 of Clinical Study 2019nCoV-101, a two-dose regimen of 5 µg or 25 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant administered 21 days (+ 7 days) apart as a co-formulated drug product continued to induce robust immune responses that were markedly higher than those from either one-dose 5 µg or 25 µg adjuvanted regimens or placebo in participants 18 to 84 years of age. Based on these early clinical data, the two-dose regimen of 5 µg SARS-CoV-2 rS with 50-µg Matrix-M adjuvant (also referred to as NVX-CoV2373), administered 21 days (+ 7 days) apart as a co-formulation was selected for late-stage clinical development in Clinical Studies 2019nCoV-501, 2019nCoV-302, and 2019nCoV-301.

**Table 2.5-8: Key Immunogenicity Results Across the SARS-CoV-2 rS Clinical Development Program**

| Clinical Study | Key Immunogenicity Results | Interim Report Cross-Reference |
|---|---|---|
| 2019nCoV-101 (Part 1) | • **Anti-S protein IgG GMTs and SCRs (≥ 4-fold change) following first and second vaccination in the 5 µg two-dose adjuvanted group, 25 µg two-dose adjuvanted group, 25 µg one-dose adjuvanted group, 25 µg two-dose unadjuvanted group, and placebo group, with SARS-CoV-2 rS and Matrix-M adjuvant administered separately as a bedside mixture 21 days (+ 7 days) apart, were (primary immunogenicity endpoint):**<br>o Day 21 anti-S protein GMTs: 1984.2, 2625.9, 3317.2, 189.2, and 109.7 EU/mL, respectively (Table 7).<br>o Day 35 anti-S protein GMTs: 63160.4, 47521.0, 2932.0, 575.5, and 113.5 EU/mL, respectively.<br>o Day 21 anti-S protein SCRs: 89.7%, 92.6%, 96.2%, 12.0%, and 0.0%, respectively.<br>o Day 35 anti-S protein SCRs: 100.0%, 100.0%, 96.2%, 60.0%, and 0.0%, respectively.<br>• **Anti-S protein IgG GMTs, GMFR, SCRs, and SRRs at Days 0, 7, 21, 28, 35, 49, 105, and 189 are presented in Figure 1 and Table 7, with anti-S protein IgG GMTs for the 5 µg and 25 µg two-dose adjuvanted groups peaking at Day 35 and declining thereafter but remaining markedly elevated compared to placebo (secondary immunogenicity endpoint).**<br>• **hACE2 receptor binding inhibition GMTs, GMFR, SCRs, and SRRs at Days 0, 7, 21, 28, 35, 49, 105, and 189 are presented in Figure 4 and Table 8, with hACE2 receptor binding inhibition GMTs for the 5 µg and 25 µg two-dose adjuvanted groups peaking at Day 35 and declining thereafter but remaining elevated compared to placebo (secondary immunogenicity endpoint).**<br>• **Neutralizing antibody GMTs, GMFR, SCRs, and SRRs at Days 0, 21, 35, 49, and 189 are presented in Figure 7 and Table 9, with neutralizing antibody GMTs for the 5 µg and 25 µg two-dose adjuvanted groups peaking at Day 35 and declining thereafter but remaining markedly elevated compared to placebo (secondary immunogenicity endpoint).**<br>• **There were strong correlations between anti-S protein IgG and neutralization assay (Figure 11) and hACE2 receptor binding inhibition and neutralization assay (Figure 13) following both vaccinations (secondary immunogenicity endpoint).**<br>• **Antigen-specific T-cell responses of both the Th1 phenotype (Figure 14 and Table 10) and Th2 phenotype (Figure 15 and Table 11) were evident, with responses skewed toward the Th1 cytokine phenotype (secondary immunogenicity endpoint).** | Section 4.2 |

**Table 2.5-8: Key Immunogenicity Results Across the SARS-CoV-2 rS Clinical Development Program**

| Clinical Study | Key Immunogenicity Results | Interim Report Cross-Reference |
|---|---|---|
| 2019nCoV-101 (Part 2) | • **Two-dose regimens of 5 µg or 25 µg SARS-CoV-2 rS co-formulated with 50 µg Matrix-M adjuvant, administered 21 days (+ 7 days) apart, induced robust immune responses (anti-S protein IgG GMTs) in participants who received both doses of vaccine compared to placebo in healthy adult participants 18 to 84 years of age that were 2-fold higher in seropositive participants than seronegative participants (primary immunogenicity endpoint):**<br>o Anti-S protein IgG GMTs for the 5-µg and 25-µg doses at Day 35 were 44,420.9 and 46,459.3 EU/mL, respectively, vs placebo (126.1 EU/mL) in participants regardless of baseline serostatus; SCRs were 98.3%, 99.6%, and 1.3%, respectively (Table 10).<br>o Anti-S protein IgG GMTs for the 5-µg and 25-µg doses at Day 35 were 43,865.2 and 45,045.2 EU/mL, respectively, vs placebo (117.2 EU/mL) in seronegative participants; SCRs were 98.7%, 99.6%, and 1.3%, respectively (Table 11).<br>o Anti-S protein IgG GMTs for the 5-µg and 25-µg doses at Day 35 were 93,360.8 and 127,714.2 EU/mL, respectively, vs placebo (2,126.9 EU/mL) in seropositive participants; SCRs were 75.0%, 100.0%, and 0.0%, respectively (Table 12).<br>• **Two-dose regimens of 5 µg or 25 µg SARS-CoV-2 rS co-formulated with 50 µg Matrix-M adjuvant, administered 21 days (+ 7 days) apart, induced robust immune responses (anti-S protein IgG GMTs and SCRs) in participants 18 to 84 years of age regardless of baseline serostatus compared to one-dose regimens and placebo (secondary immunogenicity endpoint):**<br>o Anti-S protein IgG GMTs for the 5-µg and 25-µg doses at Day 35 in the two-dose regimen were 43,749.0 and 45,675.7 EU/mL, respectively, vs one-dose regimens (871.8 and 1,948.8 EU/mL) and placebo (125.6 EU/mL) (Table 13).<br>o Anti-S protein IgG SCRs for the 5-µg and 25-µg doses at Day 35 in the two-dose regimen were 98.3% and 99.6%, respectively, vs one-dose regimens (66.7% and 86.8%) and placebo (1.2%).<br>• **Two-dose regimens of 5 µg or 25 µg SARS-CoV-2 rS co-formulated with 50 µg Matrix-M adjuvant, administered 21 days (+ 7 days) apart, induced robust immune responses (anti-S protein IgG, hACE2 receptor binding inhibition, and neutralizing antibody GMTs and SCRs), with an approximate 2-fold attenuation of immune response seen in older participants 60 to 84 years of age but with comparable SCRs to those in participants 18 to 59 years of age (secondary immunogenicity endpoints):**<br>o 18 to 59 years of age at Day 35 GMTs: 65,019.1 and 58,773.8 EU/mL; 115.7 and 143.1 titer units; and 2,200.8 and 1,783.1, respectively (Table 15, Table 22, and Table 29, respectively).<br>o 60 to 84 years of age at Day 35 GMTs: 28,136.6 and 32,871.2 EU/mL; 50.8 and 78.7 titer units; and 980.5 and 1,034.2, respectively (Table 15, Table 22, and Table 29, respectively).<br>o 18 to 59 years of age at Day 35 SCRs: 99.2% and 100.0%; 89.5% and 98.5%; and 100.0% and 100.0%, respectively.<br>o 60 to 84 years of age at Day 35 SCRs: 97.4% and 99.0%; 71.1% and 83.8%; and 100.0% and 96.2%, respectively.<br>• **Two-dose adjuvanted vaccine groups had the strongest antigen-specific T-cell responses, with relative skew toward the Th1 cytokine pathway (Figure 16 and Table 34 for the Th1 pathway and Figure 17 and Table 35 for the Th2 pathway).** | Section 4.2 |

**Table 2.5-8: Key Immunogenicity Results Across the SARS-CoV-2 rS Clinical Development Program**

| Clinical Study | Key Immunogenicity Results | Interim Report Cross-Reference |
|---|---|---|
| 2019nCoV-501 | • **NVX-CoV2373, administered 21 days (+ 7 days) apart, induced robust immune responses (anti-S protein IgG and neutralizing antibody) in both HIV-negative and HIV-positive participants (secondary immunogenicity endpoint). For participants who were seronegative at baseline, immune responses were approximately 2-fold greater for HIV-negative participants than they were for HIV-positive participants but were comparable when participants in these 2 groups were seropositive at baseline, indicating that priming by prior infection (with SARS-CoV-2) enables baseline seropositive HIV-positive participants to mount an immune response comparable to baseline seropositive HIV-negative participants.**<br>o Anti-S protein IgG GMTs and SCRs (≥ 4-fold change) were elevated at Day 35 vs placebo in HIV-negative and HIV-positive participants ≥ 18 to ≤ 84 years of age regardless of baseline serostatus (46,151.1 vs 337.1 EU/mL and 98.4% vs 6.0%, respectively), seronegative at baseline (30,520.6 vs 126.0 EU/mL and 99.4% vs 3.6%, respectively), and seropositive at baseline (100,534.1 vs 1,738.3 EU/mL and 97.0% vs 10.0%, respectively) (Table 28).<br>o Anti-S protein IgG GMTs and SCRs (≥ 4-fold change) were elevated at Day 35 vs placebo in HIV-negative participants ≥ 18 to ≤ 84 years of age regardless of baseline serostatus (47,103.8 vs 334.9 EU/mL and 98.5% vs 5.9%, respectively), seronegative at baseline (31,631.8 vs 125.0 EU/mL and 99.3% vs 3.4%, respectively), and seropositive at baseline (100,666.1 vs 1,730.9 EU/mL and 97.3% vs 10.1%, respectively) (Table 29).<br>o Anti-S protein IgG GMTs and SCRs (≥ 4-fold change) were elevated at Day 35 vs placebo in HIV-positive participants ≥ 18 to ≤ 84 years of age regardless of baseline serostatus (31,210.8 vs 379.1 EU/mL and 96.9% vs 7.8%, respectively), seronegative at baseline (14,420.5 vs 146.5 EU/mL and 100.0% vs 7.8%, respectively), and seropositive at baseline (98,399.5 vs 1,880.2 EU/mL and 92.3% vs 7.9%, respectively) (Table 30).<br>o Neutralizing antibody GMTs and SCRs (≥ 4-fold change) were elevated at Day 35 vs placebo in HIV-negative and HIV-positive participants ≥ 18 to ≤ 84 years of age regardless of baseline serostatus (1,160.0 vs 21.2 and 97.1% vs 6.4%, respectively), seronegative at baseline (688.0 vs 10.9 and 97.1% vs 2.2%, respectively), and seropositive at baseline (3,083.7 vs 64.3 and 97.1% vs 13.4%, respectively) (Table 32).<br>o Neutralizing antibody GMTs and SCRs (≥ 4-fold change) were elevated at Day 35 vs placebo in HIV-negative participants ≥ 18 to ≤ 84 years of age regardless of baseline serostatus (1,188.1 vs 21.2 and 97.2% vs 6.3%, respectively), seronegative at baseline (714.7 vs 10.8 and 97.1% vs 2.0%, respectively), and seropositive at baseline (3,105.0 vs 64.4 and 97.4% vs 13.4%, respectively) (Table 33).<br>o Neutralizing antibody GMTs and SCRs (≥ 4-fold change) were elevated at Day 35 vs placebo in HIV-positive participants ≥ 18 to ≤ 84 years of age regardless of baseline serostatus (740.3 vs 21.9 and 96.0% vs 8.9%, respectively), seronegative at baseline (320.0 vs 12.0 and 98.4% vs 6.3%, respectively), and seropositive at baseline (2,748.6 vs 61.5 and 92.3% vs 13.5%, respectively) (Table 34). | Section 4.3 |

**Table 2.5-8: Key Immunogenicity Results Across the SARS-CoV-2 rS Clinical Development Program**

| Clinical Study | Key Immunogenicity Results | Interim Report Cross-Reference |
|---|---|---|
| 2019nCoV-302 (Main Study) | • **NVX-CoV2373, administered 21 days (+ 7 days) apart, induced markedly increased anti-S protein IgG GMTs and SCRs relative to placebo, overall and across both age groups (secondary immunogenicity endpoint):**<br>o Anti-S protein IgG GMTs and SCRs (≥ 4-fold change) were elevated at Day 35 vs placebo in baseline seronegative participants who received both ≥ 18 to ≤ 84 years of age (44,678.3 vs 113.2 EU/mL and 99.0% vs 0.7%, respectively), ≥ 18 to ≤ 64 years of age (47,564.3 vs 113.5 EU/mL and 99.0% vs 1.0%, respectively), and ≥ 65 to ≤ 84 years of age (37,892.8 vs 112.3 EU/mL and 99.0% vs 1.0%, respectively) (Table 33).<br>o Anti-S protein IgG GMTs and SCRs (≥ 4-fold change) were elevated at Day 35 vs placebo regardless of baseline serostatus ≥ 18 to ≤ 84 years of age (46,679.3 vs 129.5 EU/mL and 98.9% vs 1.1%, respectively), ≥ 18 to ≤ 64 years of age (50,659.6 vs 127.6 EU/mL and 98.8% vs 1.5%, respectively), and ≥ 65 to ≤ 84 years of age (37,494.5 vs 135.1 EU/mL and 99.2% vs 0.0%, respectively) (Table 34).<br>o Anti-S protein IgG GMTs and SCRs (≥ 4-fold change) were elevated at Day 35 vs placebo in participants ≥ 18 to ≤ 84 years of age seronegative or seropositive at baseline (46,679.3 vs 129.5 EU/mL and 98.9% vs 1.1%, respectively), seronegative at baseline (44,229.9 vs 115.4 EU/mL and 99.1% vs 1.2%, respectively), and seropositive at baseline (125,489.8 vs 1,756.9 EU/mL and 95.7% vs 0.0%, respectively) (Table 35).<br>• **NVX-CoV2373, administered 21 days (+ 7 days) apart, induced markedly increased neutralizing antibody GMTs and SCRs relative to placebo, overall and across both age groups (secondary immunogenicity endpoint):**<br>o Neutralizing antibody GMTs and SCRs (≥ 4-fold change) were elevated at Day 35 vs placebo in baseline seronegative participants ≥ 18 to ≤ 84 years of age (1,133.1 vs 10.4 and 98.2% vs 0.5%, respectively), ≥ 18 to ≤ 64 years of age (1,241.2 vs 10.5 and 98.1% vs 0.7%, respectively), and ≥ 65 to ≤ 84 years of age (907.9 vs 10.0 and 98.2% vs 0.0%, respectively) (Table 36).<br>o Neutralizing antibody GMTs and SCRs (≥ 4-fold change) were elevated at Day 35 vs placebo regardless of baseline serostatus ≥ 18 to ≤ 84 years of age (1,214.6 vs 11.3 and 98.9% vs 1.1%, respectively), ≥ 18 to ≤ 64 years of age (1,345.2 vs 11.2 and 98.3% vs 1.6%, respectively), and ≥ 65 to ≤ 84 years of age (940.6 vs 11.7 and 98.3% vs 1.0%, respectively) (Table 37).<br>o Neutralizing antibody GMTs and SCRs (≥ 4-fold change) were elevated at Day 35 vs placebo in participants ≥ 18 to ≤ 84 years of age seronegative or seropositive at baseline (1,214.6 vs 11.3 and 98.3% vs 1.5%, respectively), seronegative at baseline (1,129.5 vs 10.4 and 98.2% vs 0.8%, respectively), and seropositive at baseline (4,373.8 vs 62.0 and 100.0% vs 15.8%, respectively) (Table 38). | Section 4.3 |

| | | |
|---|---|---|
| 2019nCoV-302 (Seasonal Influenza Vaccine Substudy) | • **There was no evidence for immune interference of NVX-CoV2373 when administered concomitantly with influenza vaccines. Day 21 HAI GMTs for all 4 influenza strains were not statistically significantly different between the NVX-CoV2373 and placebo groups (exploratory immunogenicity endpoint).**<br>o For the QIVc group, Day 21 HAI GMTs for the Influenza A H1N1 and H3N2 strains were numerically higher in the NVX-CoV2373 group than in the placebo group (195.7 vs 158.7, respectively, in participants 18 to 84 years of age and 198.0 vs 162.1 in participants 18 to 64 years of age for H1N1 and 246.9 vs 219.6 and 253.0 vs 221.0 for H3N2) and similar between the NVX-CoV2373 and placebo groups for the B strains (9.9 vs 9.7 and 9.8 vs 9.2 for Victoria and 36.9 vs 36.5 and 39.2 vs 38.1 for Yamagata) (Table 7).<br>o For the smaller aTIV group, which comprised only H1N1, H3N2 and B/Victoria, Day 21 HAI GMTs were more variable between the NVX-CoV2373 and the placebo groups (167.1 vs 112.8 for H1N1; 176.3 vs 199.0 for H3N2 and; 11.0 vs 21.9 for Victoria; and 16.0 vs 18.1 for Yamagata) probably due to the small number of participants in this group (Table 7).<br>o For both QIVc and aTIV, Day 21 HAI SCRs were generally high for the Influenza A strains and lower for the Influenza B strains.<br>• **In a post-hoc analysis, NVX-CoV2373 elicited a robust anti-S protein response versus placebo at Day 35 that was diminished by approximately 30% in comparison to participants not administered an influenza vaccine on Day 0 (2109nCoV-302, the Main Study); however, SCRs remained similar.**<br>o Anti-S protein IgG GMTs in seronegative participants in the NVX-CoV2373 group were diminished by 30.1% (44,673.8 vs 31,236.1 EU/mL, respectively, for serologically negative participants 18 to 84 years of age), 33.7% (47,564.3 vs 31,516.9 EU/mL for participants 18 to 64 years of age), and 29.1% (37,892.8 vs 26,876.1 EU/mL for participants 65 to 84 years of age) when compared with the levels reported in the Main Study (Table 9).<br>o Anti-S protein IgG SCRs in seronegative SARS-CoV-2 participants in the NVX-CoV2373 group were similar (97.8% vs 99.0% for participants 18 to 84 years of age; 97.6% vs 99.0% for participants 18 to 64 years of age; and 100.0% vs 99.1% for participants 65 to 84 years of age) to those reported in the Main Study.<br>o Anti-S protein IgG GMTs in participants regardless of baseline SARS-CoV-2 serostatus in the NVX-CoV2373 group were diminished by 29.9% (46,679.3 vs 32,724.4 EU/mL, respectively, for participants 18 to 84 years of age), 32.1% (50,659.6 vs 34,413.5 EU/mL for participants 18 to 64 years of age), and 54.8% (37,494.5 vs 16,953.4 EU/mL for participants 65 to 84 years of age) when compared with the levels reported in the Main Study (Table 10).<br>o Anti-S protein IgG SCRs in participants regardless of baseline SARS-CoV-2 serostatus in the NVX-CoV2373 group were similar (97.6% vs 98.9% for participants 18 to 84 years of age; 97.4% vs 98.8% for participants 18 to 64 years of age; and 100.0% vs 99.2% for participants 65 to 84 years of age) to those reported in the Main Study.<br>o Anti-S protein IgG GMTs in participants by SARS-CoV-2 serostatus in the NVX-CoV2373 group were diminished by 29.9% (46,679.3 vs 32,724.4 EU/mL, respectively, for serologically negative and positive participants), 31.2% (44,229.9 vs 30,439.1 EU/mL for serologically negative participants), and 43.3% (125,489.8 vs 71,115.6 EU/mL for serologically positive participants) when compared with the levels reported in the Main Study (Table 11).<br>o Anti-S protein IgG SCRs in participants by SARS-CoV-2 serostatus in the NVX-CoV2373 group were similar (97.6% vs 98.9% for serologically negative and positive participants; 97.9% vs 99.1% for serologically negative participants; and 94.4% vs 95.7% for serologically positive participants) to those reported in the Main Study. | Section 4.3 |

Abbreviations: anti-S = anti-spike; aTIV = adjuvanted trivalent influenza vaccine; CI = confidence interval; COVID-19 = coronavirus disease 2019; ELISA = enzyme-linked immunosorbent assay; EU/mL = ELISA units per milliliter; GMFR = geometric mean fold rise; GMT = geometric mean titer; hACE2 = human angiotensin-converting enzyme 2; HAI = hemagglutination inhibition; HIV = human immunodeficiency virus; IgG = immunoglobulin G; NVX-CoV2373 = 5 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant; QIVc = quadrivalent influenza vaccine (unadjuvanted); SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine; SCR = seroconversion rate; SRR = seroresponse rate; Th1 = Type 1 T helper; Th2 = Type 2 T helper.

Note, the bioanalytical assays used in each of these clinical studies are summarized in Table 2.5-3.

### 2.5.5.3 Immunogenicity Conclusions

- Two-dose regimens of 5 µg or 25 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant, administered 21 days (+ 7 days) apart as a bedside mixture in Clinical Study 2019nCoV-101 (Part 1), induced robust immune responses (anti-S protein IgG, wild-type neutralizing, and hACE2 receptor binding inhibition), peaking 2 weeks after second vaccination (Day 35) compared to a one-dose 25 µg adjuvanted regimen, a two-dose 25 µg unadjuvanted regimen, or placebo in healthy adult participants 18 to 59 years of age. Matrix-M adjuvant was antigen sparing, induced high levels of functional antibodies, and showed a Th1-biased immune response. No dose response was seen between the 5-µg and 25-µg doses. Notably, a strong correlation was observed between anti-S protein IgG levels or hACE2 receptor binding inhibition and neutralizing antibodies from Day 35 through Day 189.
- Two-dose regimens of 5 µg or 25 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant, administered 21 days (+ 7 days) apart as co-formulated drug product in Part 2 of Clinical Study 2019nCoV-101, showed similar results (to Part 1) in healthy adult participants 18 to 84 years of age, regardless of baseline serostatus, at Day 35 with an approximate 2-fold attenuation of immune response seen in older participants 60 to 84 years of age. Collectively, the data from Part 1 and Part 2 of Clinical Study 2019nCoV-101 supported selection and further development of the two-dose 5 µg adjuvanted vaccine.
- A two-dose regimen of NVX-CoV2373, administered 21 days (+ 7 days) apart, similarly induced robust immune responses (anti-S protein IgG and neutralizing antibody) in healthy HIV-negative South African participants 18 to 84 years of age and medically stable HIV-positive participants 18 to 64 years of age in Clinical Study 2019nCoV-501. For participants who were seronegative at baseline, anti-S protein IgG immune responses were approximately 2-fold greater for HIV-negative participants than for HIV-positive participants but were comparable when participants in these 2 groups were seropositive at baseline, indicating that priming by prior infection (with SARS-CoV-2) enables baseline seropositive HIV-positive participants to mount an immune response comparable to baseline seropositive HIV-negative participants.
- A two-dose regimen of NVX-CoV2373, administered 21 days (+ 7 days) apart, similarly induced robust immune responses (anti-S protein IgG and neutralizing antibody) relative to placebo in adult participants 18 to 84 years of age in Clinical Study 2019nCoV-302 with higher levels in the younger adult cohort (18 to 64 years) than in the older adult cohort (65 to 84 years) but with similarly high SCRs.
- Co-administration of a licensed seasonal influenza vaccine on Day 0 in Clinical Study 2019nCoV-302 showed that there was no statistically significant effect of NVX-CoV2373 on HAI GMTs of 4 influenza strains following first vaccination (Day 21). In a post-hoc analysis, a two-dose regimen of NVX-CoV2373, administered 21 days (+ 7 days) apart, elicited a robust anti-S protein IgG response versus placebo at Day 35 that was diminished by approximately 30% in comparison to participants not co-administered with an influenza vaccine on Day 0; however, SCRs remained similar. This effect was also seen in participants 18 to 64 years of age but not in participants 65 to 84 years of age due too few participants in the older age stratum, although anti-S protein IgG response was vigorous in this group.

# 2.5.6 OVERVIEW OF SAFETY

## 2.5.6.1 Safety Evaluation Plan

Safety data supporting the SARS-CoV-2 rS clinical development program include both nonclinical and clinical studies. In the nonclinical setting, SARS-CoV-2 rS with Matrix-M adjuvant has demonstrated a robust and functional immune response along with protective efficacy in live viral challenge studies across multiple species. Moreover, no treatment-related adverse effects have been identified in Good Laboratory Practice (GLP)-compliant repeated-dose toxicity and developmental and reproductive toxicity studies. Histopathology has been confined to expected local injection site inflammation which was reversible. Pulmonary histopathology in SARS-CoV-2 challenge studies has identified no evidence of vaccine-enhanced respiratory disease. Together, these data support the proposed dose and regimen for human use (ie, 5 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant administered on Days 0 and 21 [+ 7 days]).

In the clinical setting, the safety of NVX-CoV2373 (5 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant) is being evaluated in each clinical study. Safety assessments include monitoring and recording of solicited (local and systemic reactogenicity events), unsolicited treatment-emergent adverse events (TEAEs), serious adverse events (SAEs), medically attended adverse events (MAAEs), adverse events of special interest (AESI), and vital sign measurements. Safety laboratory values (hematology and serum chemistry) were also evaluated in the first-in-human Clinical Study 2019nCoV-101 (Part 1).

In each study, vital sign measurements were collected once before vaccination and again at 30 (+ 15) minutes after vaccination to monitor immediate reactions to the vaccine. For Clinical Studies 2019nCoV-101 (Part 1 and Part 2), 2019nCoV-501, and 2019nCoV-302, vaccination pause rules based on reactogenicity, safety laboratory results (Clinical Study 2019nCoV-101 [Part 1] only), and SAEs related to study participation were in place to monitor participant safety during the study.

For each study, a safety monitoring committee (SMC), or Data and Safety Monitoring Board (DSMB) in Clinical Study 2019nCoV-301, was formed before the first participant was vaccinated and reviewed study progress and participant, clinical, safety, and reactogenicity data for immediate concerns regarding observations during this study, to allow advancement in a study (ie, Part 1 to Part 2 in Clinical Study 2019nCoV-101), or to suggest modifications to the study design, as needed. As an added safety precaution in Clinical Study 2019nCoV-101 (Part 1), the first 6 participants enrolled into the study (ie, sentinel participants) were administered active vaccine in an open-label manner and observed over a 2-day period before the remaining participants enrolled into the study. In Clinical Study 2019nCoV-101 (Part 2), enrollment of older participants was paused until adequate reactogenicity data was accrued before enrolling the remaining participants. A similar pause was implemented in Clinical Study 2019nCoV-501 for both the enrollment of older participants and HIV-positive participants. Ultimately, the SMC or DSMB did not recommend stopping or modifying any trial due to safety concerns, and all studies proceeded as planned.

Safety objectives and endpoints are described in Section 2 of Clinical Study 2019nCoV-101 (Part 1), Section 2 of Clinical Study 2019nCoV-101 (Part 2), Section 2 of Clinical Study 2019nCoV-501, Section 2 of Clinical Study 2019nCoV-501, and Section 2 of Clinical Study 2019nCoV-301.

A pooled analysis of safety data across the SARS-CoV-2 rS clinical development program was performed to further evaluate the safety of NVX-CoV2373 (Section 2.5.6.7).

### 2.5.6.2 Nonclinical Information Related to Safety

The nonclinical program has demonstrated that SARS-CoV-2 rS with Matrix-M adjuvant generates a robust and functional immune response, eliciting neutralizing antibodies against SARS-CoV-2, resulting in protective efficacy following live viral challenge across multiple species. No adverse risks have been identified in the nonclinical testing program to date and the data support the proposed dose and regimen for human use (ie, 5 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant administered on Days 0 and 21 [+ 7 days]). Studies across multiple species immunized with SARS-CoV-2 rS with Matrix-M adjuvant, including non-human primate models administered the intended human dose, have shown no evidence of vaccine-enhanced disease following challenge with live SARS-CoV-2 virus, even when the vaccine was administered at suboptimal doses (ie, single doses and/or lower antigen/adjuvant doses). In the GLP repeat-dose toxicity study, 50 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant was well tolerated with non-adverse findings limited to local injection site inflammation and serum chemical markers of inflammation (ie, elevated globulins, fibrinogen, and C-reactive protein), which were transient and considered consistent with immune system stimulation consequent to immunization. A GLP developmental and reproductive toxicity study in rats indicates no adverse findings on fertility, pregnancy/lactation, or development of the embryo/fetus and offspring through post-natal Day 21. Taken as a whole, the nonclinical data supported evaluation of both 5-µg and 25-µg doses of SARS-CoV-2 rS with and without Matrix-M adjuvant in the clinical development program and supports licensure/authorization at the proposed dose and regimen.

In addition, the totality of toxicology data obtained in rat and rabbit GLP studies, which have evaluated Matrix-M adjuvant alone or co-administered with different nanoparticle vaccine antigens manufactured using the same platform technology as the SARS-CoV-2 rS antigen, has failed to demonstrate overt systemic or organ-specific toxicities and Matrix-M adjuvant administration was generally well-tolerated. Lastly, two GLP-compliant in vitro genotoxicity studies (Ames and mammalian cell micronucleus) confirm that Matrix-M adjuvant is non-mutagenic.

Please reference Module 2.4 for additional details regarding the nonclinical program.

### 2.5.6.3 Clinical Information Related to Safety

#### 2.5.6.3.1 Extent of Exposure

Table 2.5-9 summarizes the extent of exposure of participants who received NVX-CoV2373 (5 µg SARS-CoV-2 rS + 50 µg Matrix-M adjuvant) and placebo across the SARS-CoV-2 rS clinical development program. Extent of exposure was defined as the number of participants who received

either both doses of trial vaccine or placebo or only 1 dose of trial vaccine or placebo during the initial vaccination period of each study. Over 96% of NVX-CoV2373 recipients and over 91% of placebo recipients received both doses of trial vaccine.

**Table 2.5-9: Extent of Exposure Across SARS-CoV-2 rS Clinical Development Program**

| Exposure | 2019nCoV-101 | | 2019nCoV-501 | 2019nCoV-302 | 2019nCoV-301 |
|---|---|---|---|---|---|
| | Part 1[1] | Part 2[2] | | | |
| **NVX-CoV2373 (5 µg SARS-CoV-2 rS + 50 µg Matrix-M adjuvant)** | | | | | |
| 2 doses, n (%) | 29/29 (100.0) | 509/514 (99.0) | 2140/2211 (96.8) | 7467/7569 (98.7) | 19104/19729 (96.8) |
| 1 dose, n (%) | 0 | 5/514 (1.0) | 71/2211 (3.2) | 102/7569 (1.3) | 625/19729 (3.2) |
| **Placebo** | | | | | |
| 2 doses, n (%) | 21/23 (91.3) | 250/255 (98.0) | 2120/2197 (96.5) | 7463/7570 (98.6) | 9422/9853 (95.6) |
| 1 dose, n (%) | 2/23 (8.7) | 5/255 (2.0) | 77/2197 (3.5) | 107/7570 (1.4) | 431/9853 (4.4) |

Abbreviations: SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine.

1. Group C (5 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant on Days 0 and 21 [+ 7 days]) only.
2. Groups B (5 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant on Days 0 and 21 [+ 7 days]) and C (5 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant on Day 0 and placebo on Day 21 [+ 7 days]) only.

### 2.5.6.3.2 Solicited Local and Systemic Adverse Events

Table 2.5-10 and Table 2.5-11, respectively, summarize the solicited local and systemic TEAEs by study across the SARS-CoV-2 rS clinical development program among participants who received NVX-CoV2373 (or equivalent 5-µg dose of SARS-CoV2373 in Clinical Studies 2019nCoV-101 [Part 1] and 2019nCoV-101 [Part 2]).

Overall, there were higher frequencies of solicited local and systemic TEAEs among NVX-CoV2373 recipients than among placebo recipients following each vaccination. In the NVX-CoV2373 group, the frequency and intensity of solicited local and systemic TEAEs increased after second vaccination relative to the first vaccination in all studies except Clinical Study 2019nCoV-501 but the trial vaccine remained well tolerated. Most participants in the NVX-CoV2373 group reported grade 1 or grade 2 local and systemic events following each vaccination. Frequencies of grade 3 events were relatively low (< 10% for local and < 15% for systemic), but such events did generally occur more frequently in the NVX-CoV2373 group than in the placebo group; grade 4 events were reported in relatively few participants. The most frequent (incidence > 20.0%) solicited local TEAEs following each vaccination were tenderness and pain, with median durations of 2.0 and 1.0 days, respectively, following each vaccination. The most frequent (incidence > 20.0%) solicited systemic TEAEs following each vaccination were fatigue, headache, and muscle pain, which had median durations of 1.0 day following each vaccination. Across the 2 age strata, older participants reported a lower frequency and intensity of solicited local and systemic TEAEs than younger participants.

**Table 2.5-10: Solicited Local Adverse Events for 7 Days Following Each Vaccination Across the SARS-CoV-2 rS Clinical Development Program**

| Clinical Trial | 2019nCoV-101 (Part 1)[1] | | 2019nCoV-101 (Part 2)[2] | | 2019nCoV-501[3] | | 2019nCoV-302[4] | | 2019nCoV-301 | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Trial Vaccine Group** | **NVX** | **Placebo** | **NVX** | **Placebo** | **NVX** | **Placebo** | **NVX** | **Placebo** | **NVX** | **Placebo** |
| **N1/N2** | **26/26[5]** | **23/21** | **508/250[6]** | **252/242** | **2211/2141** | **2197/2124** | **1285/1203** | **1272/1172** | **18072/17139** | **8904/8278** |
| **Any local TEAE** | | | | | | | | | | |
| Dose 1 (Grade ≥ 1) | 18 (69.2) | 7 (30.4) | 266 (52.4) | 39 (15.5) | 659 (29.8) | 320 (14.6) | 762 (59.3) | 266 (20.9) | 10475 (57.96) | 1881 (21.13) |
| Grade 3 | 0 | 0 | 1 (0.2) | 0 | 32 (1.4) | 7 (0.3) | 14 (1.1) | 2 (0.2) | 197 (1.09) | 22 (0.25) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (< 0.01) | 1 (0.01) |
| Dose 2 (Grade ≥ 1) | 24 (92.3) | 4 (19.0) | 175 (70.0) | 22 (9.1) | 616 (28.8) | 225 (10.6) | 965 (80.2) | 199 (17.0) | 13525 (78.91) | 1797 (21.71) |
| Grade 3 | 0 | 0 | 13 (5.2) | 0 | 52 (2.4) | 9 (0.4) | 63 (5.2) | 1 (< 0.1) | 1140 (6.65) | 25 (0.30) |
| Grade 4 | 0 | 0 | 0 | 0 | 8 | 0 | 0 | 0 | 7 (0.04) | 1 (0.01) |
| **Pain** | | | | | | | | | | |
| Dose 1 (Grade ≥ 1) | 10 (38.5) | 3 (13.0) | 139 (27.4) | 10 (4.0) | 595 (26.9) | 261 (11.9) | 394 (30.7) | 130 (10.2) | 6211 (34.37) | 986 (11.07) |
| Grade 3 | 0 | 0 | 0 | 0 | 23 (1.0) | 4 (0.2) | 1 (< 0.1) | 1 (< 0.1) | 55 (0.30) | 3 (0.03) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dose 2 (Grade ≥ 1) | 15 (57.7) | 2 (9.5) | 114 (45.6) | 9 (3.7) | 570 (26.6) | 184 (8.7) | 624 (51.9) | 107 (9.1) | 10227 (59.67) | 1141 (13.78) |
| Grade 3 | 0 | 0 | 5 (2.0) | 0 | 41 (1.9) | 8 (0.4) | 11 (0.9) | 0 | 297 (1.73) | 7 (0.08) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 5 (0.03) | 1 (0.01) |
| **Tenderness** | | | | | | | | | | |
| Dose 1 (Grade ≥ 1) | 17 (65.4) | 7 (30.4) | 244 (48.0) | 33 (13.1) | 360 (16.3) | 166 (7.6) | 705 (54.9) | 223 (17.5) | 9450 (52.29) | 1494 (16.78) |
| Grade 3 | 0 | 0 | 1 (0.2) | 0 | 19 (0.9) | 2 (< 0.1) | 14 (1.1) | 1 (< 0.1) | 156 (0.86) | 18 (0.20) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (< 0.01) | 1 (0.01) |
| Dose 2 (Grade ≥ 1) | 21 (80.8) | 2 (9.5) | 163 (65.2) | 18 (7.4) | 369 (17.2) | 133 (6.3) | 922 (76.6) | 164 (14.0) | 12584 (73.42) | 1312 (15.85) |
| Grade 3 | 0 | 0 | 9 (3.6) | 0 | 31 (1.4) | 1 (< 0.1) | 49 (4.1) | 1 (< 0.1) | 834 (4.87) | 18 (0.22) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 (0.02) | 0 |

**Table 2.5-10: Solicited Local Adverse Events for 7 Days Following Each Vaccination Across the SARS-CoV-2 rS Clinical Development Program**

| Clinical Trial | 2019nCoV-101 (Part 1)[1] | | 2019nCoV-101 (Part 2)[2] | | 2019nCoV-501[3] | | 2019nCoV-302[4] | | 2019nCoV-301 | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Trial Vaccine Group** | **NVX** | **Placebo** | **NVX** | **Placebo** | **NVX** | **Placebo** | **NVX** | **Placebo** | **NVX** | **Placebo** |
| **N1/N2** | **26/26[5]** | **23/21** | **508/250[6]** | **252/242** | **2211/2141** | **2197/2124** | **1285/1203** | **1272/1172** | **18072/17139** | **8904/8278** |
| **Erythema** | | | | | | | | | | |
| Dose 1 (Grade ≥ 1) | 0 | 0 | 3 (0.6) | 0 | 17 (0.8) | 5 ( 0.2) | 25 (1.9) | 5 (0.4) | 164 (0.91) | 27 (0.30) |
| Grade 3 | 0 | 0 | 0 | 0 | 1 (< 0.1) | 1 (< 0.1) | 0 | 0 | 3 (0.02) | 0 |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dose 2 (Grade ≥ 1) | 2 (7.7) | 1 (4.8) | 12 (4.8) | 0 | 34 (1.6) | 3 ( 0.1) | 100 (8.3) | 2 (0.2) | 1138 (6.64) | 29 (035) |
| Grade 3 | 0 | 0 | 3 (1.2) | 0 | 0 | 0 | 11 (0.9) | 0 | 143 (0.83) | 2 (0.02) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Swelling** | | | | | | | | | | |
| Dose 1 (Grade ≥ 1) | 0 | 0 | 5 (1.0) | 1 (0.4) | 18 (0.8) | 5 (0.2) | 12 (0.9) | 6 (0.5) | 154 (0.85) | 24 (0.27) |
| Grade 3 | 0 | 0 | 0 | 0 | 0 | 1 (< 0.1) | 0 | 0 | 7 (0.04) | 3 (0.03) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Dose 2 (Grade ≥ 1) | 1 (3.8) | 0 | 14 (5.6) | 0 | 45 (2.1) | 4 (0.2) | 89 (7.4) | 4 (0.3) | 1056 (6.16) | 25 (0.30) |
| Grade 3 | 0 | 0 | 1 (0.4) | 0 | 1 (<0.1) | 0 | 5 (0.4) | 0 | 91 (0.53) | 2 (0.02) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Abbreviations: FDA = United States Food and Drug Administration; N1 = number of participants receiving the first dose of trial vaccine; N2 = number of participants receiving the second dose of trial vaccine; NVX = NVX-CoV2373; NVX-CoV2373 = 5 µg SARS-CoV-2 rS + 50 µg Matrix-M adjuvant; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine; TEAE = treatment-emergent adverse events.

1. Group C only.
2. Groups B and C only.
3. Based on Table 14.3.3.1.1.3 of the 2019nCoV-501 Interim Report.
4. Solicited local and systemic TEAEs were evaluated in a subset of 2,714 participants in this study.
5. Excludes 3 sentinel participants who received active vaccine in an open-label manner.
6. Based on Group B only as participants in Group C received placebo for their second vaccination.

Note: Toxicity grading based on FDA toxicity grading scales [DHHS 2007].
Note: Data are presented as number and percentage (n, %) of participants.

**Table 2.5-11: Solicited Systemic Adverse Events for 7 Days Following Each Vaccination Across the SARS-CoV-2 rS Clinical Development Program**

| Clinical Trial | 2019nCoV-101 (Part 1)[1] | | 2019nCoV-101 (Part 2)[2] | | 2019nCoV-501[3] | | 2019nCoV-302[4] | | 2019nCoV-301 | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Trial Vaccine Group** | **NVX** | **Placebo** | **NVX** | **Placebo** | **NVX** | **Placebo** | **NVX** | **Placebo** | **NVX** | **Placebo** |
| **N1/N2** | **26/26[5]** | **23/21** | **510/250[6]** | **251/241** | **2210/2141** | **2196/2123** | **1281/1198** | **1273/1164** | **18072/17139** | **8904/8278** |
| **Any systemic TEAE** | | | | | | | | | | |
| Dose 1 (Grade ≥ 1) | 12 (46.2) | 9 (39.1) | 214 (42.0) | 91 (36.3) | 632 (28.6) | 542 (24.7) | 610 (47.6) | 482 (37.9) | 8614 (47.66) | 3562 (40.00) |
| Grade 3 | 0 | 0 | 13 (2.5) | 2 (0.8) | 54 (2.4) | 46 (2.1) | 17 (1.3) | 17 (1.3) | 422 (2.34) | 183 (2.06) |
| Grade 4 | 0 | 0 | 0 | 2 (0.8) | 0 | 0 | 2 (0.2) | 0 | 17 (0.09) | 5 (0.06) |
| Dose 2 (Grade ≥ 1) | 17 (65.4) | 7 (33.3) | 132 (52.8) | 66 (27.4) | 516 (24.1) | 366 (17.2) | 774 (64.6) | 359 (30.8) | 11906 (69.47) | 2969 (35.87) |
| Grade 3 | 2 (7.7) | 1 (4.8) | 14 (5.6) | 2 (0.8) | 71 (3.3) | 52 (2.4) | 82 (6.8) | 16 (1.4) | 2056 (12.00) | 165 (1.99) |
| Grade 4 | 0 | 0 | 0 | 1 (0.4) | 8 | 0 | 1 (< 0.1) | 0 | 21 (0.12) | 5 (0.06) |
| **Nausea or Vomiting** | | | | | | | | | | |
| Dose 1 (Grade ≥ 1) | 1 (3.8) | 1 (4.3) | 25 (4.9) | 9 (3.6) | 138 (6.2) | 109 (5.0) | 67 (5.2) | 69 (5.4) | 1152 (6.37) | 488 (5.48) |
| Grade 3 | 0 | 0 | 1 (0.2) | 0 | 4 (0.2) | 7 ( 0.3) | 0 | 0 | 17 (0.09) | 7 (0.08) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (< 0.1) | 0 | 4 (0.02) | 3 (0.03) |
| Dose 2 (Grade ≥ 1) | 2 (7.7) | 0 | 18 (7.2) | 9 (3.7) | 118 (5.5) | 81 (3.8) | 128 (10.7) | 44 (3.8) | 1929 (11.26) | 450 (5.44) |
| Grade 3 | 0 | 0 | 0 | 0 | 11 (0.5) | 6 (0.3) | 1 (< 0.1) | 0 | 29 (0.17) | 7 (0.08) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 7 (0.04) | 2 (0.02) |
| **Headache** | | | | | | | | | | |
| Dose 1 (Grade ≥ 1) | 6 (23.1) | 7 (30.4) | 97 (19.0) | 48 (19.1) | 384 (17.4) | 356 (16.2) | 314 (24.5) | 274 (21.5) | 4505 (24.93) | 2028 (22.78) |
| Grade 3 | 0 | 0 | 1 (0.2) | 1 (0.4) | 17 (0.8) | 20 (0.9) | 6 (0.5) | 3 (0.2) | 146 (0.81) | 62 (0.70) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (< 0.1) | 0 | 5 (0.03) | 1 (0.01) |
| Dose 2 (Grade ≥ 1) | 12 (46.2) | 6 (28.6) | 74 (29.6) | 31 (12.9) | 318 (14.9) | 232 (10.9) | 487 (40.7) | 208 (17.9) | 7618 (44.45) | 1625 (19.63) |
| Grade 3 | 0 | 0 | 5 (2.0) | 1 (0.4) | 39 (1.8) | 27 (1.3) | 17 (1.4) | 3 (0.3) | 512 (2.99) | 36 (0.43) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 6 (0.04) | 2 (0.02) |

**Table 2.5-11: Solicited Systemic Adverse Events for 7 Days Following Each Vaccination Across the SARS-CoV-2 rS Clinical Development Program**

| Clinical Trial | 2019nCoV-101 (Part 1)[1] | | 2019nCoV-101 (Part 2)[2] | | 2019nCoV-501[3] | | 2019nCoV-302[4] | | 2019nCoV-301 | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Trial Vaccine Group** | **NVX** | **Placebo** | **NVX** | **Placebo** | **NVX** | **Placebo** | **NVX** | **Placebo** | **NVX** | **Placebo** |
| **N1/N2** | **26/26[5]** | **23/21** | **510/250[6]** | **251/241** | **2210/2141** | **2196/2123** | **1281/1198** | **1273/1164** | **18072/17139** | **8904/8278** |
| **Fatigue** | | | | | | | | | | |
| Dose 1 (Grade ≥ 1) | 8 (30.8) | 4 (17.4) | 121 (23.7) | 52 (20.7) | 262 (11.9) | 199 (9.1) | 263 (20.5) | 244 (19.2) | 4632 (25.63) | 1993 (22.38) |
| Grade 3 | 0 | 0 | 8 (1.6) | 1 (0.4) | 20 (0.9) | 12 (0.5) | 6 (0.5) | 6 (0.5) | 224 (1.24) | 100 (1.12) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (< 0.1) | 0 | 3 (0.02) | 1 (0.01) |
| Dose 2 (Grade ≥ 1) | 12 (46.2) | 3 (14.3) | 89 (35.6) | 33 (13.7) | 209 (9.8) | 137 (6.5) | 491 (41.0) | 194 (16.7) | 8486 (49.51) | 1811 (21.88) |
| Grade 3 | 1 (3.8) | 1 (4.8) | 7 (2.8) | 1 (0.4) | 19 (0.9) | 14 (0.7) | 43 (3.6) | 9 (0.8) | 1419 (8.28) | 108 (1.30) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4 (0.02) | 3 (0.04) |
| **Malaise** | | | | | | | | | | |
| Dose 1 (Grade ≥ 1) | 3 (11.5) | 2 (8.7) | 62 (12.2) | 30 (12.0) | 164 (7.4) | 127 (5.8) | 149 (11.6) | 122 (9.6) | 2660 (14.72) | 1037 (11.65) |
| Grade 3 | 0 | 0 | 8 (1.6) | 0 | 10 (0.5) | 8 (0.4) | 4 (0.3) | 4 (0.3) | 137 (0.76) | 53 (0.60) |
| Grade 4 | 0 | 0 | 0 | 1 (0.4) | 0 | 0 | 1 (< 0.1) | 0 | 7 (0.04) | 2 (0.02) |
| Dose 2 (Grade ≥ 1) | 9 (34.6) | 3 (14.3) | 66 (26.4) | 19 (7.9) | 148 (6.9) | 88 (4.1) | 377 (31.5) | 107 (9.2) | 6674 (38.94) | 1018 (12.30) |
| Grade 3 | 0 | 0 | 6 (2.4) | 0 | 14 (0.7) | 10 (0.5) | 34 (2.8) | 7 (0.6) | 1073 (6.26) | 57 (0.69) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 9 (0.05) | 2 (0.02) |
| **Muscle pain** | | | | | | | | | | |
| Dose 1 (Grade ≥ 1) | 6 (23.1) | 2 (8.7) | 103 (20.2) | 27 (10.8) | 261 (11.8) | 171 (7.8) | 286 (22.3) | 181 (14.2) | 4102 (22.70) | 1188 (13.34) |
| Grade 3 | 0 | 0 | 2 (0.4) | 0 | 20 (0.9) | 6 (0.3) | 1 (< 0.1) | 4 (0.3) | 81 (0.45) | 35 (0.39) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (< 0.1) | 0 | 2 (0.01) | 2 (0.02) |
| Dose 2 (Grade ≥ 1) | 12 (46.2) | 3 (14.3) | 77 (30.8) | 16 (6.6) | 249 (11.6) | 110 (5.2) | 492 (41.1) | 113 (9.7) | 8240 (48.08) | 1001 (12.09) |
| Grade 3 | 1 (3.8) | 0 | 6 (2.4) | 0 | 22 (1.0) | 14 (0.7) | 34 (2.8) | 3 (0.3) | 841 (4.91) | 29 (0.35) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 5 (0.03) | 4 (0.05) |

**Table 2.5-11: Solicited Systemic Adverse Events for 7 Days Following Each Vaccination Across the SARS-CoV-2 rS Clinical Development Program**

| Clinical Trial | 2019nCoV-101 (Part 1)[1] | | 2019nCoV-101 (Part 2)[2] | | 2019nCoV-501[3] | | 2019nCoV-302[4] | | 2019nCoV-301 | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Trial Vaccine Group** | **NVX** | **Placebo** | **NVX** | **Placebo** | **NVX** | **Placebo** | **NVX** | **Placebo** | **NVX** | **Placebo** |
| **N1/N2** | **26/26[5]** | **23/21** | **510/250[6]** | **251/241** | **2210/2141** | **2196/2123** | **1281/1198** | **1273/1164** | **18072/17139** | **8904/8278** |
| **Joint pain** | | | | | | | | | | |
| Dose 1 (Grade ≥ 1) | 1 (3.8) | 1 (4.3) | 38 (7.5) | 15 (6.0) | 196 (8.9) | 158 (7.2) | 84 (6.6) | 63 (4.9) | 1388 (7.68) | 590 (6.63) |
| Grade 3 | 0 | 0 | 2 (0.4) | 0 | 18 (0.8) | 4 (0.2) | 0 | 2 (0.2) | 51 (0.28) | 29 (0.33) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (< 0.1) | 0 | 1 (< 0.01) | 0 |
| Dose 2 (Grade ≥ 1) | 7 (26.9) | 2 (9.5) | 37 (14.8) | 9 (3.7) | 180 (8.4) | 109 (5.1) | 205 (17.1) | 59 (5.1) | 3809 (22.22) | 567 (6.85) |
| Grade 3 | 1 (3.8) | 0 | 3 (1.2) | 0 | 20 (0.9) | 8 (0.4) | 24 (2.0) | 2 (0.2) | 411 (2.40) | 24 (0.29) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 6 (0.04) | 2 (0.02) |
| **Fever** | | | | | | | | | | |
| Dose 1 (Grade ≥ 1) | 0 | 0 | 12 (2.4) | 6 (2.4) | 33 (1.5) | 32 (1.5) | 28 (2.3) | 19 (1.5) | 66 (0.37) | 33 (0.37) |
| Grade 3 | 0 | 0 | 3 (0.6) | 0 | 5 (0.2) | 7 (0.3) | 5 (0.4) | 2 (0.2) | 8 (0.04) | 6 (0.07) |
| Grade 4 | 0 | 0 | 0 | 1 (0.4) | 0 | 0 | 1 (< 0.1) | 0 | 6 (0.03) | 1 (0.01) |
| Dose 2 (Grade ≥ 1) | 0 | 0 | 11 (4.4) | 2 (0.8) | 48 (2.2) | 27 (1.3) | 59 (5.1) | 9 (0.8) | 973 (5.68) | 23 (0.28) |
| Grade 3 | 0 | 0 | 1 (0.4) | 0 | 6 (0.3) | 6 (0.3) | 7 (0.6) | 2 (0.2) | 62 (0.36) | 3 (0.04) |
| Grade 4 | 0 | 0 | 0 | 1 (0.4) | 0 | 0 | 1 (< 0.1) | 0 | 2 (0.01) | 0 |

Abbreviations: FDA = United States Food and Drug Administration; TEAE = treatment-emergent adverse events; N1 = number of participants receiving the first dose of trial vaccine; N2 = number of participants receiving the second dose of trial vaccine; NVX = NVX-CoV2373; NVX-CoV2373 = 5 µg SARS-CoV-2 rS + 50 µg Matrix-M adjuvant; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine.

1. Group C only.
2. Groups B and C only.
3. Based on Table 14.3.3.12.3 of the 2019nCoV-501 Interim Report.
4. Solicited local and systemic TEAEs were evaluated in a subset of 2,714 participants in this study.
5. Excludes 3 sentinel participants who received active vaccine in an open-label manner.
6. Based on Group B only as participants in Group C received placebo for their second vaccination.

Note: Toxicity grading based on FDA toxicity grading scales [DHHS 2007].
Note: Data are presented as number and percentage (n, %) of participants.

### 2.5.6.4 Overall Summary of Adverse Events

Table 2.5-12 summarizes the adverse event (AE) profile of NVX-CoV2373 by study across the NVX-CoV2373 clinical development program. Unsolicited TEAEs, especially unsolicited related TEAEs, tended to be reported at a higher frequency in the NVX-CoV2373 group than in the placebo group. Most unsolicited TEAEs were mild or moderate in severity. Severe TEAEs and SAEs were reported infrequently and at similar frequencies between the 2 treatment groups; this was also true for TEAEs leading to vaccination or study discontinuation, MAAEs, and AESIs. A total of 21 deaths has been reported, with 13 deaths in the NVX-CoV2373 group and 8 deaths in the placebo group. None of the deaths in NVX-CoV2373 recipients were assessed as related to study vaccination.

**Table 2.5-12: Overall Summary of Unsolicited Adverse Events Across the SARS-CoV-2 rS Clinical Development Program**

| Unsolicited Adverse Event Parameters | 2019nCoV-101 (Part 1)[1] | | 2019nCoV-101 (Part 2)[2] | | 2019nCoV-501 | | 2019nCoV-302 | | 2019nCoV-301 | |
|---|---|---|---|---|---|---|---|---|---|---|
| | NVX | Placebo | NVX | Placebo | NVX | Placebo | NVX | Placebo | NVX | Placebo |
| | N = 26[3] | N = 23 | N = 514 | N = 255 | N = 2211 | N = 2197 | N = 7570 | N = 7569 | N = 19729 | N = 9853 |
| Any unsolicited TEAEs[4] | 14 (53.8) | 9 (39.1) | 86 (16.7) | 42 (16.5) | 329 (14.9) | 327 (14.9) | 1802 (23.8) | 1414 (18.7) | 3216 (16.3) | 1456 (14.8) |
| Severe | 0 | 0 | 5 (1.0) | 3 (1.2) | 15 (0.7) | 18 (0.8) | 58 (0.8) | 48 (0.6) | 250 (1.3) | 108 (1.1) |
| Related | 7 (26.9) | 1 (4.3) | 7 (1.4) | 6 (2.4) | 70 (3.2) | 51 (2.3) | 819 (10.8) | 341 (4.5) | 798 (4.0) | 239 (2.4) |
| Severe/related | 0 | 0 | 1 (0.2) | 0 | 2 (< 0.1) | 1 (< 0.1) | 13 (0.2) | 3 (< 0.1) | 55 (0.3) | 10 (0.1) |
| Any deaths[5] | 0 | 0 | 0 | 0 | 2 (< 0.1) | 2 (< 0.1) | 2 (< 0.1) | 1 (< 0.1) | 9 (0.5) | 5 (0.5) |
| Related[6] | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Any SAEs[5] | 0 | 0 | 5 (1.0) | 2 (0.8) | 11 (0.5) | 18 (0.8) | 41 (0.5) | 41 (0.5) | 169 (0.9) | 94 (1.0) |
| Related[6] | 0 | 0 | 1 (0.2) | 0 | 0 | 0 | 0 | 0 | 2 (< 0.1) | 0 |
| Any TEAEs leading to vaccination discontinuation[5] | 0 | 0 | 4 (0.8) | 4 (1.6) | 0 | 1 (< 0.1) | 23 (0.3) | 22 (0.3) | 57 (0.3) | 16 (0.2) |
| Related | 0 | 0 | 1 (0.2) | 1 (0.4) | 0 | 0 | 7 (< 0.1) | 8 (0.1) | 10 (0.1) | 3 (< 0.1) |
| Any TEAEs leading to study discontinuation[5] | 0 | 0 | 1 (0.2) | 2 (0.8) | 4 (0.2) | 4 (0.2) | 17 (0.2) | 16 (0.2) | 60 (0.3) | 13 (0.1) |
| Related | 0 | 0 | 0 | 0 | 0 | 1 (< 0.1) | 5 (< 0.1) | 2 (< 0.1) | 14 (0.1) | 2 (< 0.1) |
| MAAEs[5] | 5 (19.2) | 6 (26.1) | 33 (6.4) | 14 (5.5) | 29 (1.3) | 34 (1.5) | 285 (3.8) | 295 (3.9) | 1387 (7.0) | 651 (6.6) |
| Related | 2 (7.7) | 1 (4.3) | 1 (0.2) | 2 (0.8) | 2 (< 0.1) | 1 (< 0.1) | 33 (0.4) | 13 (0.2) | 92 (0.5) | 30 (0.3) |
| Any AESI: PIMMCs[5] | 0 | 0 | 0 | 1 (0.4)[5] | 0 | 1 (< 0.1)[7] | 5 (< 0.1)[8] | 7 (< 0.1)[8] | 28 (0.14)[9] | 13 (0.13)[9] |
| Any AESI: related to COVID-19[5] | 0 | 0 | 0 | 0 | 15 (0.7) | 29 (1.3) | 8 (0.1) | 22 (0.3) | 4 (< 0.1) | 4 (< 0.1) |

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

1. Group C only.
2. Groups B and C only.
3. Excludes 3 sentinel participants who received active vaccine in an open-label manner.
4. Events reported within 28 days after second vaccination (eg, Day 49) or within 14 days after second vaccination (eg, Day 35) in Clinical Study 2019nCoV-101 (Part 2).
5. Events reported as of the data cutoff date for each respective study.
6. According to both the investigator and the sponsor.
7. Based on investigator's discretion.
8. Revised PIMMC definition: PIMMC events identified via preferred term, per protocol.
9. Based on both investigator's discretion and revised PIMMC definition (ie, protocol-specified criteria).

Note: Data are presented as number and percentage (n, %) of participants.

#### 2.5.6.4.1 Adverse Events in Subpopulations

##### 2.5.6.4.1.1 Solicited Local TEAEs

Subgroup analyses by demographic and baseline characteristics were performed for solicited local TEAEs in Clinical Study 2019nCoV-301 (see Section 4.3.3.3 and Table 28 in 2019nCoV-301 Interim Report), in which:

- Participants in the older age cohort (≥ 65 years of age) reported lower frequencies and intensities of solicited local TEAEs among NVX-CoV2373 recipients after each vaccination than in participants in the younger age cohort (18 to ≤ 64 years of age).
- Male participants reported lower frequencies and intensities of solicited local TEAEs among both NVX-CoV2373 and placebo recipients after each vaccination than in female participants.
- Black or African American participants reported lower frequencies and intensities of solicited local TEAEs among NVX-CoV2373 recipients after each vaccination than in participants of other races.
- There were generally similar frequencies and intensities of solicited local TEAEs after each vaccination among White, Asian, American Indian/Alaska Native, Native Hawaiian/Other Pacific Islander, and multiple race participants in the NVX-CoV2373 group.
- There were similar frequencies and intensities of solicited local TEAEs after each vaccination among not Hispanic or Latino and Hispanic or Latino participants in the NVX-CoV2373 group.
- Participants in the US reported lower frequencies and intensities of solicited local TEAEs among both NVX-CoV2373 and placebo recipients after each vaccination than in participants in Mexico.
- Participants with co-morbidities of obesity, chronic kidney disease, cardiovascular disease, and diabetes mellitus type 2 reported lower frequencies and intensities of solicited local TEAEs after each vaccination among NVX-CoV2373 recipients than participants with chronic lung disease.
- There were similar frequencies and intensities of solicited local TEAEs after each vaccination among high risk and not high risk participants in the NVX-CoV2373 group.

##### 2.5.6.4.1.2 Solicited Systemic TEAEs

Subgroup analyses by demographic and baseline characteristics were performed for solicited systemic TEAEs in Clinical Study 2019nCoV-301 (see Section 4.3.3.6 and Table 32, respectively, in 2019nCoV-301 Interim Report), in which:

- Participants in the older age cohort (≥ 65 years of age) reported lower frequencies and intensities of solicited systemic TEAEs among NVX-CoV2373 recipients after each vaccination than in participants in the younger age cohort (18 to ≤ 64 years of age).

- Male participants reported lower frequencies and intensities of solicited systemic TEAEs among both NVX-CoV2373 and placebo recipients after each vaccination than in female participants.
- Black or African American participants reported lower frequencies of solicited systemic TEAEs among NVX-CoV2373 recipients after each vaccination than in participants of other races.
- Black or African American participants also reported lower intensities of solicited systemic TEAEs among NVX-CoV2373 recipients after second vaccination than in participants of other races.
- There were generally similar frequencies and intensities of solicited systemic TEAEs after each vaccination among White, Asian, American Indian/Alaska Native, Native Hawaiian/Other Pacific Islander, and multiple race participants in the NVX-CoV2373 group.
- There were similar frequencies and intensities of solicited systemic TEAEs after each vaccination among not Hispanic or Latino and Hispanic or Latino participants in the NVX-CoV2373 group.
- Participants in the US reported lower frequencies of solicited systemic TEAEs among both NVX-CoV2373 and placebo recipients after each vaccination than in participants in Mexico.
- Participants with co-morbidities of obesity, chronic kidney disease, cardiovascular disease, and diabetes mellitus type 2 reported lower frequencies and intensities of solicited systemic TEAEs after each vaccination among NVX-CoV2373 recipients than participants with chronic lung disease.
- There were generally similar frequencies and intensities of solicited local TEAEs after each vaccination among high risk and not high risk participants in the NVX-CoV2373 group.

#### 2.5.6.4.1.3 Seasonal Influenza Vaccine Substudy

NVX-CoV2373 was well tolerated in a subset of approximately 400 participants in the Seasonal Influenza Vaccine Substudy of Clinical Study 2019nCoV-302, with a similar safety profile to that of the Main Study except that solicited local and systemic TEAEs were reported at higher frequencies in both the NVX-CoV2373 and placebo groups following first vaccination in the Seasonal Influenza Vaccine Substudy (see Section 4.4 of the 2019nCoV-302 Interim Report Flu Substudy for details).

- In the Substudy, the frequencies of solicited local TEAEs following first vaccination across the overall population and 2 age strata in the NVX-CoV2373 group were 70.1%, 72.7%, and 38.5%, respectively, for participants 18 to 84, 18 to 64, and 65 to 84 years of age and 39.4%, 39.1%, and 45.5%, respectively, in the placebo group (Table 13, Table 14, and Table 15, respectively).

- In the Main Study, the frequencies of solicited local TEAEs following first vaccination across the overall population and 2 age strata in the NVX-CoV2373 group were 57.6%, 63.0%, and 34.9%, respectively, for participants 18 to 84 years of age, 18 to 64

years of age, and 65 to 84 years of age and 17.9%, 20.5%, and 7.6%, respectively, in the placebo group (Table 13, Table 14, and Table 15, respectively).

- In the Substudy, the frequencies of solicited systemic TEAEs following first vaccination across the overall population and 2 age strata in the NVX-CoV2373 group were 60.1%, 61.9%, and 38.5%, respectively, for participants 18 to 84, 18 to 64, and 65 to 84 years of age and 47.2%, 46.7%, and 54.5%, respectively, in the placebo group (Table 19, Table 20, and Table 21, respectively).
- In the Main Study, the frequencies of solicited systemic TEAEs following first vaccination across the overall population and 2 age strata in the NVX-CoV2373 group were 45.7%, 49.8%, and 28.3%, respectively, for participants 18 to 84 years of age, 18 to 64 years of age, and 65 to 84 years of age and 36.3%, 39.6%, and 23.6%, respectively, in the placebo group (Table 19, Table 20, and Table 21, respectively).
- After second vaccination, the frequencies of solicited local and systemic TEAEs were similar between the substudy and Main Study (Table 13, Table 14, Table 15, Table 19, Table 20, and Table 21, respectively).

### 2.5.6.5 Adverse Drug Reactions

Adverse drug reactions included the solicited local TEAEs of injection site pain, tenderness, erythema, and swelling and solicited systemic TEAEs of fatigue, headache, muscle pain, malaise, joint pain, nausea or vomiting, and fever.

### 2.5.6.6 Safety in Special Populations

Clinical Study 2019nCoV-501 evaluated the safety of NVX-CoV2373 in 244 medically stable HIV-positive participants 18 to ≤ 64 years of age (122 in each treatment group). Across the safety assessments, the safety profile of NVX-CoV2373 in HIV-positive participants was similar to that seen in HIV-negative participants.

### 2.5.6.7 Pooled Analysis of Safety Data

#### 2.5.6.7.1 Introduction

A pooled analysis of safety data was performed across the SARS-CoV-2 rS clinical development program to further evaluate the safety of NVX-CoV2373, the 5-µg dose of SARS-CoV-2 rS with 50 µg Matrix-M adjuvant proposed for licensure. This dose was used in the 2 pivotal Phase 3 efficacy studies, 2019nCoV-302 (UK) and 2019nCoV-301 (US and Mexico), and the Phase 2a/b efficacy, 2019nCoV-501 (South Africa). For the earlier clinical studies, 2019nCoV-101 (Part 1) and 2019nCoV-101 (Part 2), only safety data from the 5-µg adjuvanted dose (Group C in Part 1 and Groups B and C in Part 2) and placebo (Group A in both Part 1 and Part 2 were used in the pooled analysis.

The pooled analysis of safety data included data collected from after the start of first vaccination through the data cutoff dates of the respective clinical studies included in the analysis, with the exception that safety data collected after booster dosing in Clinical Studies 2019nCoV-101 (Part 2) and 2019nCoV-501 or after blinded crossover dosing in Clinical

Studies 2019nCoV-302 and 2019nCoV-301 and safety data collected after study unblinding were censored and excluded from this pooled analysis.

Details regarding the statistical analyses performed in the pooled analysis of safety data are provided in the Statistical Analysis Plan for the Integrated Summary of Safety of Novavax SARS-COV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-COV-2 rS) With Matrix-M™ Adjuvant, SAP Version 2.0, July 12, 2021. It is acknowledged that a pooled analysis of safety data is presented herein as agreed with global regulators in the interest of submitting the application in an expedited manner in the context of a global pandemic. A complete pooled analysis of safety data will be filed subsequently following initial approvals as part of applications for full authorization/approval.

### 2.5.6.7.2 Extent of Exposure

The pooled analysis of safety data comprised 30,058 participants who received NVX-CoV2373 and 19,892 participants who received placebo across the SARS-CoV-2 rS clinical development program (Table 2.5-13), with over 96% of NVX-CoV2373 and placebo recipients receiving both doses of trial vaccine/placebo (Table 2.5-14).

**Table 2.5-13: Number of Participants by Trial Included in the Pooled Analysis of Safety Data**

| Study Number | NVX-CoV2373 | Placebo |
|---|---|---|
| 2019nCoV-101 | 543 | 278 |
| 2019nCoV-101 - Part 1[1] | 29 | 23 |
| 2019nCoV-101 - Part 2[2] | 514 | 255 |
| 2019nCoV-501 [3] | 2211 | 2197 |
| 2019nCoV-302 [4] | 7575[5] | 7564[5] |
| 2019nCoV-301 | 19729 | 9853 |
| **Total** | **30058** | **19892** |

Abbreviations: HIV = human immunodeficiency virus; 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.

1. Included Groups A (placebo) and C (two-dose regimen of 5 µg SARS-CoV-2 rS with 50 µg Matrix-M Adjuvant) only.
2. Included Groups A (placebo), B (two-dose regimen of 5 µg SARS-CoV-2 rS with 50 µg Matrix-M Adjuvant), and C (5 µg SARS-CoV-2 rS with 50 µg Matrix-M Adjuvant at Dose 1 and placebo at Dose 2) only.
3. Included approximately 240 participants who were HIV-positive in the total population.
4. Included approximately 400 participants who were co-administered seasonal influenza vaccine at Dose 1.
5. These numbers differ from those reported in the 2019nCoV-302 Interim Report (7,569 in the NVX-CoV2373 group and 7,570 in the placebo group) because safety data for 6 participants who received a mixed regimen (placebo at dose 1 and active vaccine at dose 2) were included in the active vaccine group only for the purposes of the pooled analysis of safety data.

Source: T1

**Table 2.5-14: Exposure of Participants in the Pooled Analysis of Safety Data**

| Number of Doses Received | NVX-CoV2373 | Placebo |
|---|---|---|
| Total exposure | 30058 | 19892 |
| 2 doses | 28963 (96.4%) | 19270 (96.9%) |
| 1 dose[1] | 1095 (3.6%) | 622 (3.1%) |

Abbreviations: 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.

1. Participants receiving a mixed regimen are included in the pooled analysis of safety data as receiving 1 dose of the active vaccine and only the data post the active vaccine dose are included in the analysis. They were not included in the analysis of short-term safety post the second dose of the active vaccine.

Source: T2

### 2.5.6.7.3 Demographics

Demographic characteristics of participants in the pooled analysis were generally well balanced between the NVX-CoV2373 and placebo groups, with slightly lower frequencies of participants ≥ 65 years of age and participants of Black or African American race and a slightly higher frequency of participants of Hispanic or Latino origin in the NVX-CoV2373 group (Table 2.5-15).

**Table 2.5-15: Demographic Characteristics of Participants in the Pooled Analysis of Safety Data**

| Demographic Characteristics | NVX-CoV2373 N = 30058 n (%) | Placebo N = 19892 n (%) | Total N = 49950 |
|---|---|---|---|
| **Age** | | | |
| 18 to 64 years | 25282 (84.11) | 16433 (82.61) | 41715 |
| ≥ 65 years | 4776 (15.89) | 3459 (17.39) | 8235 |
| **Sex** | | | |
| Male | 15826 (52.65) | 10364 (52.10) | 26190 |
| Female | 14232 (47.35) | 9528 (47.90) | 23760 |
| **Race** | | | |
| White | 22415 (74.57) | 14808 (74.44) | 37223 |
| Black or African American | 4417 (14.69) | 3256 (16.37) | 7673 |
| Asian | 1119 (3.72) | 691 (3.47) | 1810 |
| American Indian or Alaska Native | 1322 (4.40) | 665 (3.34) | 1987 |
| Native Hawaiian or Other Pacific Islander | 58 (0.19) | 13 (0.07) | 71 |
| Multiple | 463 (1.54) | 260 (1.31) | 723 |
| Not Reported | 209 (0.70) | 134 (0.67) | 343 |
| Other | 43 (0.14) | 54 (0.27) | 97 |
| Missing | 12 (0.04) | 11 (0.06) | 23 |
| **Ethnicity** | | | |
| Hispanic/Latino | 4463 (14.85) | 2262 (11.37) | 6725 |
| Not Hispanic/Latino | 24647 (82.00) | 16747 (84.19) | 41394 |
| Not Reported | 780 (2.59) | 726 (3.65) | 1506 |
| Unknown | 161 (0.54) | 152 (0.76) | 313 |

**Table 2.5-15: Demographic Characteristics of Participants in the Pooled Analysis of Safety Data**

| Demographic Characteristics | NVX-CoV2373 N = 30058 n (%) | Placebo N = 19892 n (%) | Total N = 49950 |
|---|---|---|---|
| Missing | 7 (0.02) | 5 (0.03) | 12 |

Abbreviations: 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.
Source: T3

### 2.5.6.7.4 Solicited Adverse Events

As described in each of the individual clinical studies across the SARS-CoV-2 rS clinical development program, there were higher frequencies of solicited local and systemic TEAEs among NVX-CoV2373 recipients than among placebo recipients following each vaccination in each age cohort (Table 2.5-16 and Table 2.5-17). In the NVX-CoV2373 group, the frequency and intensity of solicited local and systemic TEAEs increased after second vaccination relative to the first vaccination but the study vaccine remained well tolerated. Most participants in the NVX-CoV2373 group reported grade 1 or grade 2 local and systemic events following each vaccination. Frequencies of grade 3 events were relatively low (< 10% for local and < 15% for systemic), but such events did generally occur more frequently in the NVX-CoV2373 group than in the placebo group; grade 4 events were reported in relatively few participants. The most frequent (incidence > 20.0%) solicited local TEAEs following each vaccination were tenderness and pain. The most frequent (incidence > 20.0%) solicited systemic TEAEs following each vaccination were fatigue, muscle pain, and headache. Across the 2 age strata, participants in the older age cohort (≥ 65 years of age) reported a lower frequency and intensity of solicited local and systemic TEAEs than participants in the younger age cohort (18 to ≤ 64 years of age).

**Table 2.5-16: Solicited Local and Systemic Adverse Events Reported Within 7 Days of Each Vaccination (Day 0 to Day 6) in Participants 18 to 64 Years of Age in the Pooled Analysis of Safety Data**

| Solicited Local and Systemic Adverse Events | NVX-CoV2373 | | Placebo | |
|---|---|---|---|---|
| | Dose 1 N = 19436 n (%) | Dose 2 N = 18340 n (%) | Dose 1 N = 11153 n (%) | Dose 2 N = 10488 n (%) |
| **Solicited local adverse events** | | | | |
| Any local (Grade ≥ 1) | 11192 (57.58) | 13852 (75.53) | 2296 (20.59) | 2058 (19.62) |
| Grade 3 | 229 (1.18) | 1206 (6.58) | 28 (0.25) | 32 (0.31) |
| Grade 4 | 1 (<0.01) | 7 (0.04) | 1 (<0.01) | 1 (<0.01) |
| Pain (Grade ≥ 1) | 6846 (35.22) | 10570 (57.63) | 1276 (11.44) | 1320 (12.59) |
| Grade 3 | 75 (0.39) | 340 (1.85) | 7 (0.06) | 14 (0.13) |
| Grade 4 | 0 | 5 (0.03) | 0 | 1 (<0.01) |

**Table 2.5-16: Solicited Local and Systemic Adverse Events Reported Within 7 Days of Each Vaccination (Day 0 to Day 6) in Participants 18 to 64 Years of Age in the Pooled Analysis of Safety Data**

| Solicited Local and Systemic Adverse Events | NVX-CoV2373 | | Placebo | |
|---|---|---|---|---|
| | Dose 1 N = 19436 n (%) | Dose 2 N = 18340 n (%) | Dose 1 N = 11153 n (%) | Dose 2 N = 10488 n (%) |
| Tenderness (Grade ≥ 1) | 9902 (50.95) | 12731 (69.42) | 1752 (15.71) | 1501 (14.31) |
| Grade 3 | 179 (0.92) | 888 (4.84) | 19 (0.17) | 19 (0.18) |
| Grade 4 | 1 (<0.01) | 3 (0.02) | 1 (<0.01) | 0 |
| Erythema (Grade ≥ 1) | 190 (0.98) | 1162 (6.34) | 32 (0.29) | 31 (0.30) |
| Grade 3 | 4 (0.02) | 148 (0.81) | 1 (<0.01) | 2 (0.02) |
| Grade 4 | 0 | 0 | 0 | 0 |
| Swelling (Grade ≥ 1) | 170 (0.87) | 1066 (5.81) | 35 (0.31) | 26 (0.25) |
| Grade 3 | 6 (0.03) | 88 (0.48) | 4 (0.04) | 1 (<0.01) |
| Grade 4 | 0 | 0 | 0 | 0 |
| **Solicited systemic adverse events** | | | | |
| Any systemic (Grade ≥ 1) | 9239 (47.54) | 12205 (66.55) | 4240 (38.02) | 3427 (32.68) |
| Grade 3 | 466 (2.40) | 2129 (11.61) | 234 (2.10) | 216 (2.06) |
| Grade 4 | 17 (0.09) | 20 (0.11) | 6 (0.05) | 6 (0.06) |
| Nausea or vomiting (Grade ≥ 1) | 1284 (6.61) | 2068 (11.28) | 638 (5.72) | 542 (5.17) |
| Grade 3 | 22 (0.11) | 39 (0.21) | 14 (0.13) | 13 (0.12) |
| Grade 4 | 5 (0.03) | 7 (0.04) | 3 (0.03) | 2 (0.02) |
| Headache (Grade ≥ 1) | 4906 (25.24) | 7932 (43.25) | 2486 (22.29) | 1930 (18.40) |
| Grade 3 | 157 (0.81) | 555 (3.03) | 82 (0.74) | 64 (0.61) |
| Grade 4 | 5 (0.03) | 5 (0.03) | 1 (<0.01) | 2 (0.02) |
| Fatigue (Grade ≥ 1) | 4855 (24.98) | 8592 (46.85) | 2278 (20.42) | 1991 (18.98) |
| Grade 3 | 235 (1.21) | 1425 (7.77) | 114 (1.02) | 119 (1.13) |
| Grade 4[f] | 4 (0.02) | 4 (0.02) | 1 (<0.01) | 3 (0.03) |
| Malaise (Grade ≥ 1) | 2776 (14.28) | 6766 (36.89) | 1202 (10.78) | 1119 (10.67) |
| Grade 3 | 145 (0.75) | 1085 (5.92) | 61 (0.55) | 67 (0.64) |
| Grade 4 | 8 (0.04) | 9 (0.05) | 2 (0.02) | 2 (0.02) |
| Muscle pain (Grade ≥ 1) | 4426 (22.77) | 8440 (46.02) | 1419 (12.72) | 1120 (10.68) |
| Grade 3 | 101 (0.52) | 870 (4.74) | 41 (0.37) | 43 (0.41) |
| Grade 4 | 3 (0.02) | 5 (0.03) | 2 (0.02) | 4 (0.04) |
| Joint pain (Grade ≥ 1) | 1546 (7.95) | 3932 (21.44) | 736 (6.60) | 670 (6.39) |
| Grade 3 | 65 (0.33) | 440 (2.40) | 30 (0.27) | 31 (0.30) |
| Grade 4 | 2 (0.01) | 5 (0.03) | 0 | 2 (0.02) |

**Table 2.5-16: Solicited Local and Systemic Adverse Events Reported Within 7 Days of Each Vaccination (Day 0 to Day 6) in Participants 18 to 64 Years of Age in the Pooled Analysis of Safety Data**

| Solicited Local and Systemic Adverse Events | NVX-CoV2373 | | Placebo | |
|---|---|---|---|---|
| | Dose 1 N = 19436 n (%) | Dose 2 N = 18340 n (%) | Dose 1 N = 11153 n (%) | Dose 2 N = 10488 n (%) |
| Fever (Grade ≥ 1) | 121 (0.62) | 1046 (5.70) | 78 (0.70) | 49 (0.47) |
| Grade 3 | 19 (0.10) | 73 (0.40) | 14 (0.13) | 9 (0.09) |
| Grade 4 | 6 (0.03) | 3 (0.02) | 2 (0.02) | 1 (<0.01) |

Abbreviations: 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.
Source: T8.1.1_1a, T8.1.1_2a, T9.1.1_1a, T9.1.1_2a

**Table 2.5-17: Solicited Local and Systemic Adverse Events Reported Within 7 Days of Each Vaccination (Day 0 to Day 6) in Participants ≥ 65 Years of Age in the Pooled Analysis of Safety Data**

| Solicited Local and Systemic Adverse Events | NVX-CoV2373 | | Placebo | |
|---|---|---|---|---|
| | Dose 1 N = 2673 n (%) | Dose 2 N = 2392 n (%) | Dose 1 N = 1498 n (%) | Dose 2 N = 1346 n (%) |
| **Solicited local adverse events** | | | | |
| Any local (Grade ≥ 1) | 994 (37.19) | 1448 (60.54) | 216 (14.42) | 188 (13.97) |
| Grade 3 | 15 (0.56) | 62 (2.59) | 3 (0.20) | 3 (0.22) |
| Grade 4 | 0 | 0 | 0 | 0 |
| Pain (Grade ≥ 1) | 508 (19.00) | 976 (40.80) | 114 (7.61) | 122 (9.06) |
| Grade 3 | 4 (0.15) | 14 (0.59) | 1 (0.07) | 1 (0.07) |
| Grade 4 | 0 | 0 | 0 | 0 |
| Tenderness (Grade ≥ 1) | 880 (32.92) | 1324 (55.35) | 170 (11.35) | 127 (9.44) |
| Grade 3 | 11 (0.41) | 35 (1.46) | 2 (0.13) | 1 (0.07) |
| Grade 4 | 0 | 0 | 0 | 0 |
| Erythema (Grade ≥ 1) | 20 (0.75) | 125 (5.23) | 5 (0.33) | 4 (0.30) |
| Grade 3 | 0 | 9 (0.38) | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 |
| Swelling (Grade ≥ 1) | 18 (0.67) | 139 (5.81) | 1 (0.07) | 7 (0.52) |
| Grade 3 | 1 (0.04) | 10 (0.42) | 0 | 1 (0.07) |
| Grade 4 | 0 | 0 | 0 | 0 |
| **Solicited systemic adverse events** | | | | |
| Any systemic (Grade ≥ 1) | 850 (31.80) | 1129 (47.20) | 445 (29.71) | 340 (25.26) |
| Grade 3 | 41 (1.53) | 94 (3.93) | 14 (0.93) | 20 (1.49) |
| Grade 4 | 2 (0.07) | 2 (0.08) | 1 (0.07) | 0 |
| Nausea or vomiting (Grade ≥ 1) | 99 (3.70) | 126 (5.27) | 38 (2.54) | 42 (3.12) |
| Grade 3 | 0 | 2 (0.08) | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 |

**Table 2.5-17: Solicited Local and Systemic Adverse Events Reported Within 7 Days of Each Vaccination (Day 0 to Day 6) in Participants ≥ 65 Years of Age in the Pooled Analysis of Safety Data**

| Solicited Local and Systemic Adverse Events | NVX-CoV2373 | | Placebo | |
|---|---|---|---|---|
| | Dose 1 N = 2673 n (%) | Dose 2 N = 2392 n (%) | Dose 1 N = 1498 n (%) | Dose 2 N = 1346 n (%) |
| Headache (Grade ≥ 1) | 405 (15.15) | 569 (23.79) | 226 (15.09) | 172 (12.78) |
| Grade 3 | 13 (0.49) | 18 (0.75) | 4 (0.27) | 3 (0.22) |
| Grade 4 | 1 (0.04) | 1 (0.04) | 0 | 0 |
| Fatigue (Grade ≥ 1) | 434 (16.24) | 688 (28.76) | 213 (14.22) | 187 (13.89) |
| Grade 3 | 24 (0.90) | 62 (2.59) | 5 (0.33) | 14 (1.04) |
| Grade 4[f] | 0 | 0 | 0 | 0 |
| Malaise (Grade ≥ 1) | 263 (9.84) | 504 (21.07) | 115 (7.68) | 116 (8.62) |
| Grade 3 | 15 (0.56) | 41 (1.71) | 4 (0.27) | 7 (0.52) |
| Grade 4 | 0 | 0 | 1 (0.07) | 0 |
| Muscle pain (Grade ≥ 1) | 335 (12.53) | 631 (26.38) | 150 (10.01) | 123 (9.14) |
| Grade 3 | 3 (0.11) | 34 (1.42) | 4 (0.27) | 3 (0.22) |
| Grade 4 | 0 | 0 | 0 | 0 |
| Joint pain (Grade ≥ 1) | 165 (6.17) | 301 (12.58) | 91 (6.07) | 76 (5.65) |
| Grade 3 | 6 (0.22) | 19 (0.79) | 5 (0.33) | 3 (0.22) |
| Grade 4 | 0 | 1 (0.04) | 0 | 0 |
| Fever (Grade ≥ 1) | 18 (0.67) | 45 (1.88) | 12 (0.80) | 12 (0.89) |
| Grade 3 | 2 (0.07) | 3 (0.13) | 1 (0.07) | 2 (0.15) |
| Grade 4 | 1 (0.04) | 0 | 0 | 0 |

Abbreviations: 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.
Source: T8.1.2_1a, T8.1.2_2a, T9.1.2_1a, T9.1.2_2a

### 2.5.6.7.5 Unsolicited Adverse Events

Table 2.5-18 summarizes the frequencies of unsolicited TEAEs reported from after the start of first vaccination through 28 days after second vaccination (eg, Day 49) in ≥ 0.5% of participants in either treatment group. The overall frequency of unsolicited TEAEs was higher in the NVX-CoV2373 group than in the placebo across both age strata, with reactogenicity events such as fatigue, injection site pain, pyrexia, and myalgia extending beyond the 7-day post-injection window largely accounting for the differences between the 2 study groups. Between age strata, there was a higher frequency of unsolicited TEAEs among the older age stratum than among the younger age stratum.

**Table 2.5-18: Frequencies of Unsolicited Adverse Events Reported from After Start of First Vaccination Through 28 Days After Second Vaccination (eg, Day 49) in ≥ 0.5% of Participants in the Pooled Analysis of Safety Data**

| System Organ Class/Preferred Term (MedDRA Version 23.1) | Participants 18 to ≤ 64 Years | | Participants ≥ 65 Years | |
|---|---|---|---|---|
| | NVX-CoV2373 N = 25282 | Placebo N = 16433 | NVX-CoV2373 N = 4776 | Placebo N = 3459 |
| **Any unsolicited TEAE** | **4627 (18.30)** | **2577 (15.68)** | **1083 (22.68)** | **639 (18.47)** |
| **General disorders and administration site conditions** | **1610 (6.37)** | **544 (3.31)** | **407 (8.52)** | **120 (3.47)** |
| Fatigue | 478 (1.89) | 227 (1.38) | 115 (2.41) | 46 (1.33) |
| Injection site pain | 425 (1.68) | 78 (0.47) | 145 (3.04) | 21 (0.61) |
| Pyrexia | 265 (1.05) | 57 (0.35) | 34 (0.71) | 2 (0.06) |
| Chills | 144 (0.57) | 19 (0.12) | 22 (0.46) | 2 (0.06) |
| Pain | 131 (0.52) | 40 (0.24) | 22 (0.46) | 5 (0.14) |
| Injection site erythema | 78 (0.31) | 13 (0.08) | 25 (0.52) | 2 (0.06) |
| Injection site pruritus | 67 (0.27) | 5 (0.03) | 28 (0.59) | 1 (0.03) |
| **Nervous system disorders** | **1042 (4.12)** | **607 (3.69)** | **219 (4.59)** | **126 (3.64)** |
| Headache | 736 (2.91) | 390 (2.37) | 142 (2.97) | 81 (2.34) |
| **Musculoskeletal and connective tissue disorders** | **988 (3.91)** | **360 (2.19)** | **286 (5.99)** | **98 (2.83)** |
| Myalgia | 399 (1.58) | 102 (0.62) | 94 (1.97) | 22 (0.64) |
| Pain in extremity | 303 (1.20) | 58 (0.35) | 107 (2.24) | 14 (0.40) |
| Arthralgia | 142 (0.56) | 69 (0.42) | 30 (0.63) | 29 (0.84) |
| **Infections and infestations** | **666 (2.63)** | **500 (3.04)** | **143 (2.99)** | **116 (3.35)** |
| Urinary tract infection | 58 (0.23) | 43 (0.26) | 25 (0.52) | 20 (0.58) |
| **Gastrointestinal disorders** | **508 (2.01)** | **340 (2.07)** | **108 (2.26)** | **81 (2.34)** |
| Nausea | 156 (0.62) | 95 (0.58) | 24 (0.50) | 23 (0.66) |
| Diarrhoea | 144 (0.57) | 123 (0.75) | 34 (0.71) | 19 (0.55) |
| **Respiratory, thoracic and mediastinal disorders** | **494 (1.95)** | **397 (2.42)** | **110 (2.30)** | **65 (1.88)** |
| Oropharyngeal pain | 135 (0.53) | 120 (0.73) | 29 (0.61) | 18 (0.52) |
| Nasal congestion | 127 (0.50) | 93 (0.57) | 16 (0.34) | 16 (0.46) |
| Cough | 118 (0.47) | 109 (0.66) | 22 (0.46) | 11 (0.32) |
| Rhinorrhoea | 91 (0.36) | 92 (0.56) | 27 (0.57) | 18 (0.52) |
| **Skin and subcutaneous tissue disorders** | **316 (1.25)** | **165 (1.00)** | **63 (1.32)** | **29 (0.84)** |
| **Injury, poisoning and procedural complications** | **249 (0.98)** | **158 (0.96)** | **65 (1.36)** | **43 (1.24)** |
| **Psychiatric disorders** | **147 (0.58)** | **80 (0.49)** | **12 (0.25)** | **13 (0.38)** |
| **Vascular disorders** | **147 (0.58)** | **87 (0.53)** | **59 (1.24)** | **26 (0.75)** |
| Hypertension | 102 (0.40) | 70 (0.43) | 46 (0.96) | 22 (0.64) |
| **Blood and lymphatic system disorders** | **140 (0.55)** | **64 (0.39)** | **17 (0.36)** | **12 (0.35)** |
| **Investigations** | **122 (0.48)** | **83 (0.51)** | **32 (0.67)** | **19 (0.55)** |

**Table 2.5-18: Frequencies of Unsolicited Adverse Events Reported from After Start of First Vaccination Through 28 Days After Second Vaccination (eg, Day 49) in ≥ 0.5% of Participants in the Pooled Analysis of Safety Data**

| System Organ Class/Preferred Term (MedDRA Version 23.1) | Participants 18 to ≤ 64 Years | | Participants ≥ 65 Years | |
|---|---|---|---|---|
| | NVX-CoV2373 N = 25282 | Placebo N = 16433 | NVX-CoV2373 N = 4776 | Placebo N = 3459 |
| **Metabolism and nutrition disorders** | **86 (0.34)** | **65 (0.40)** | **26 (0.54)** | **8 (0.23)** |
| **Cardiac disorders** | **49 (0.19)** | **27 (0.16)** | **22 (0.46)** | **22 (0.64)** |

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine; TEAE = treatment-emergent adverse event.
Note: Frequency of TEAEs in each system organ class represents all TEAEs.
Note: Results are presented as n (%) of total number of participants in each treatment group.
Source: T13.1.1, T13.1.2

### 2.5.6.7.6 Deaths

A total of 12 (0.04%) participants in the NVX-CoV2373 group and 8 (0.04%) participants in the placebo group died as part of the pooled analysis of safety data; this analysis censored 1 participant in the NVX-CoV2373 group who died due to myocardial infarction approximately 2 months after the participant was unblinded to treatment assignment due to receipt of an EUA vaccine (this event was included in the 2019nCoV-301 Interim Report). Table 2.5-19 summarizes the IRs of deaths and events leading to death reported from after the start of first vaccination through the respective data cutoff dates for each individual study. Overall, deaths were infrequent and occurred at similar IRs in the younger age cohort and were slightly higher in the NVX-CoV2373 group than in the placebo group in the older age cohort. None of the deaths were assessed by the both the investigator and sponsor as related to study treatment. Cardiac arrest was the most frequent cause of death in both treatment groups.

**Table 2.5-19: Incidence Rates of Death Events Reported from After Start of First Vaccination Through the Respective Data Cutoff Dates of the Individual Clinical Trials in the Pooled Analysis of Safety Data**

| System Organ Class/Preferred Term (MedDRA Version 23.1) | Participants 18 to ≤ 64 Years | | Participants ≥ 65 Years | |
|---|---|---|---|---|
| | NVX-CoV2373 N1 = 25282 | Placebo N1 = 16433 | NVX-CoV2373 N1 = 4776 | Placebo N1 = 3459 |
| **Total follow-up time (person-years)** | **6337.9** | **4074.4** | **1127.1** | **802.8** |
| **Median follow-up time after first vaccination (days)** | **93** | **92** | **91** | **88** |
| **Any deaths** | **7 (0.11)** | **5 (0.12)** | **5 (0.44)[1]** | **3 (0.37)** |
| **Cardiac disorders** | **2 (0.03)** | **3 (0.07)** | **1 (0.09)** | **1 (0.12)** |
| Cardiac arrest | 2 (0.03) | 3 (0.07) | 1 (0.09) | 0 |
| Myocardial infarction | 0 | 0 | 0 | 1 (0.12) |
| **General disorders and administration site conditions** | **1 (0.02)** | **0** | **1 (0.09)** | **0** |
| Death | 0 | 0 | 1 (0.09) | 0 |
| Sudden death | 1 (0.02) | 0 | 0 | 0 |

**Table 2.5-19: Incidence Rates of Death Events Reported from After Start of First Vaccination Through the Respective Data Cutoff Dates of the Individual Clinical Trials in the Pooled Analysis of Safety Data**

| System Organ Class/Preferred Term (MedDRA Version 23.1) | Participants 18 to ≤ 64 Years | | Participants ≥ 65 Years | |
|---|---|---|---|---|
| | NVX-CoV2373 N1 = 25282 | Placebo N1 = 16433 | NVX-CoV2373 N1 = 4776 | Placebo N1 = 3459 |
| **Infections and infestations** | **2 (0.03)** | **2 (0.05)** | **1 (0.09)** | **2 (0.25)** |
| COVID-19 pneumonia | 1 (0.02)[2] | 0 | 0 | 0 |
| Septic shock | 1 (0.02) | 0 | 0 | 0 |
| COVID-19 | 0 | 2 (0.05) | 1 (0.09)[3] | 1 (0.12) |
| Bacterial sepsis | 0 | 0 | 0 | 1 (0.12) |
| **Injury, poisoning and procedural complications** | **1 (0.02)** | **0** | **1 (0.09)** | **0** |
| Gunshot wound | 1 (0.02) | 0 | 0 | 0 |
| Poisoning deliberate | 0 | 0 | 1 (0.09) | 0 |
| **Nervous system disorders** | **0** | **0** | **1 (0.09)** | **0** |
| Cerebrovascular accident | 0 | 0 | 1 (0.09) | 0 |
| **Vascular disorders** | **1 (0.02)** | **0** | **0** | **0** |
| Circulatory collapse | 1 (0.02) | 0 | 0 | 0 |

Abbreviations: COVID-19 = coronavirus disease 2019; MedDRA = Medical Dictionary for Regulatory Activities; PP-EFF = Per-Protocol Efficacy; SAE = serious adverse event; 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.

1. This analysis censored 1 participant in the NVX-CoV2373 group who died due to myocardial infarction approximately 2 months after the participant was unblinded to treatment assignment due to receipt of an EUA vaccine (this event was included in the 2019nCoV-301 Interim Report).
2. One NVX-CoV2373 participant in Clinical Study 2019nCoV-302 died due to COVID-19 pneumonia, which was reported 12 days after the first dose of vaccine; this event was excluded from the PP-EFF analysis because the event occurred before 7 days after second vaccination.
3. One NVX-CoV2373 participant in Clinical Study 2019nCoV-501 died due to COVID-19, which was reported 1 day after the participant received the second dose of vaccine; this event was excluded from the PP-EFF analysis because the event occurred before 7 days after second vaccination.

Note: Results are presented as number of events per 100 person-years, with the event rate in parentheses.
Source: T31.1.1a, T31.1.2a

### 2.5.6.7.7 Serious Adverse Events

Table 2.5-20 summarizes the IRs of unsolicited SAEs reported from after the start of first vaccination through the respective data cutoff dates for each individual study with an IR > 0.10 events per 100 person-years (e/100 PY) in any study group. SAEs occurred infrequently across both treatment groups, with slightly higher IRs among participants in the older age cohort (≥ 65 years of age). In the younger age cohort (18 to ≤ 64 years), there were no SAEs with an IR > 0.10 e/100 PY in the NVX-CoV2373 group compared with COVID-19 pneumonia (0.25), COVID-19 (0.22), and appendicitis (0.15) in the placebo group. In the older age cohort, SAEs that occurred at an IR > 0.20 e/100 PY in the NVX-CoV2373 group were COVID-19 (0.35) and prostate cancer (0.27) compared with pneumonia (0.50), COVID-19 (0.25), COVID-19 pneumonia (0.25), and atrial fibrillation (0.25) in the placebo group. Three SAEs (colitis in Clinical Study 2019nCoV-101 [Part 2] and angioedema and central

nervous system inflammation in Clinical Study 2019nCoV-301) in the NVX-CoV2373 group were assessed as related to study treatment by both the investigator and sponsor.

Of note, the IRs of SAEs in the system organ class Hepatobiliary Disorders in participants 18 to 64 years of age were 12 (0.19) in the NVX-CoV2373 group and 0 (0.00) in the placebo group. Of these 12 SAEs, 5 (0.08) were cholecystitis acute, 3 (0.05) were cholecystitis, 2 (0.03) were bile duct stone, 1 (0.02) was cholelithiasis, and 1 (0.02) was cirrhosis alcoholic; none of these events was assessed by the investigator or sponsor as related to treatment. All but 1 event was reported in Clinical Study 2019nCoV-301, with the remaining event (cholecystitis) reported in Clinical Study 2019nCoV-302. The investigator did not provide an alternate etiology for 8 events but documented that 3 events were due to a concurrent illness; 1 event was reported in a participant with a past history of the event (cirrhosis alcoholic).

**Table 2.5-20: Incidence Rates of Serious Adverse Events Reported from After Start of First Vaccination Through the Respective Data Cutoff Dates of the Individual Clinical Trials with an Incidence Rate > 0.10 %/100 PY in the Pooled Analysis of Safety Data**

| System Organ Class/Preferred Term (MedDRA Version 23.1) | Participants 18 to ≤ 64 Years | | Participants ≥ 65 Years | |
|---|---|---|---|---|
| | NVX-CoV2373 N = 25282 | Placebo N = 16433 | NVX-CoV2373 N = 4776 | Placebo N = 3459 |
| **Total follow-up time (person-year)** | **6337.9** | **4074.4** | **1127.1** | **802.8** |
| **Median follow-up time after first vaccination (days)** | **93** | **92** | **91** | **88** |
| **Any SAE** | **208 (3.28)** | **144 (3.53)** | **76 (6.74)** | **53 (6.60)** |
| **Infections and infestations** | **35 (0.55)** | **41 (1.01)** | **11 (0.98)** | **14 (1.74)** |
| Appendicitis | 6 (0.09) | 6 (0.15) | 1 (0.09) | 1 (0.12) |
| COVID-19 | 4 (0.06) | 9 (0.22) | 4 (0.35) | 2 (0.25) |
| Pneumonia | 2 (0.03) | 1 (0.02) | 2 (0.18) | 4 (0.50) |
| COVID-19 pneumonia | 1 (0.02) | 10 (0.25) | 0 (0.00) | 2 (0.25) |
| Cellulitis | 1 (0.02) | 1 (0.02) | 1 (0.09) | 1 (0.12) |
| Sepsis | 1 (0.02) | 1 (0.02) | 1 (0.09) | 1 (0.12) |
| Arthritis bacterial | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| Bacterial sepsis | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| Streptococcal bacteraemia | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| **Injury, poisoning and procedural complications** | **28 (0.44)** | **18 (0.44)** | **12 (1.06)** | **3 (0.37)** |
| Fall | 1 (0.02) | 2 (0.05) | 0 (0.00) | 1 (0.12) |
| Femur fracture | 1 (0.02) | 0 (0.00) | 2 (0.18) | 0 (0.00) |
| Wrist fracture | 1 (0.02) | 0 (0.00) | 1 (0.09) | 1 (0.12) |
| Femoral neck fracture | 0 (0.00) | 1 (0.02) | 0 (0.00) | 1 (0.12) |
| **Cardiac disorders** | **20 (0.32)** | **12 (0.29)** | **15 (1.33)** | **7 (0.87)** |
| Atrial fibrillation | 5 (0.08) | 1 (0.02) | 2 (0.18) | 2 (0.25) |
| Acute myocardial infarction | 2 (0.03) | 1 (0.02) | 2 (0.18) | 1 (0.12) |
| Myocardial infarction | 2 (0.03) | 1 (0.02) | 1 (0.09) | 1 (0.12) |
| Acute left ventricular failure | 1 (0.02) | 0 (0.00) | 2 (0.18) | 0 (0.00) |

**Table 2.5-20: Incidence Rates of Serious Adverse Events Reported from After Start of First Vaccination Through the Respective Data Cutoff Dates of the Individual Clinical Trials with an Incidence Rate > 0.10 e/100 PY in the Pooled Analysis of Safety Data**

| System Organ Class/Preferred Term (MedDRA Version 23.1) | Participants 18 to ≤ 64 Years | | Participants ≥ 65 Years | |
|---|---|---|---|---|
| | NVX-CoV2373 N = 25282 | Placebo N = 16433 | NVX-CoV2373 N = 4776 | Placebo N = 3459 |
| Atrioventricular block complete | 1 (0.02) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| Cardiac failure congestive | 1 (0.02) | 1 (0.02) | 2 (0.18) | 0 (0.00) |
| Coronary artery disease | 1 (0.02) | 1 (0.02) | 0 (0.00) | 1 (0.12) |
| Atrial tachycardia | 0 (0.00) | 0 (0.00) | 2 (0.18) | 0 (0.00) |
| Arrhythmia | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| Nervous system disorders | **20 (0.32)** | **13 (0.32)** | **3 (0.27)** | **1 (0.12)** |
| Cerebrovascular accident | 5 (0.08) | 0 (0.00) | 2 (0.18) | 1 (0.12) |
| Gastrointestinal disorders | **17 (0.27)** | **5 (0.12)** | **2 (0.18)** | **5 (0.62)** |
| Intestinal perforation | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| Nausea | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| Obstructive pancreatitis | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| Small intestinal obstruction | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| Vomiting | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| **Hepatobiliary disorders** | **12 (0.19)** | **0 (0.00)** | **0 (0.00)** | **1 (0.12)** |
| Liver injury | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| **Psychiatric disorders** | **12 (0.19)** | **8 (0.20)** | **0 (0.00)** | **2 (0.25)** |
| Suicidal ideation | 3 (0.05) | 2 (0.05) | 0 (0.00) | 1 (0.12) |
| Bipolar disorder | 2 (0.03) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| **Respiratory, thoracic and mediastinal disorders** | **12 (0.19)** | **7 (0.17)** | **5 (0.44)** | **4 (0.50)** |
| Dyspnoea | 2 (0.03) | 1 (0.02) | 0 (0.00) | 1 (0.12) |
| Pulmonary embolism | 2 (0.03) | 2 (0.05) | 2 (0.18) | 1 (0.12) |
| Acute respiratory failure | 1 (0.02) | 0 (0.00) | 2 (0.18) | 0 (0.00) |
| Asthma | 1 (0.02) | 1 (0.02) | 0 (0.00) | 1 (0.12) |
| Epistaxis | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| **Neoplasms benign, malignant and unspecified (incl cysts and polyps)** | **11 (0.17)** | **6 (0.15)** | **8 (0.71)** | **5 (0.62)** |
| Prostate cancer | 2 (0.03) | 0 (0.00) | 3 (0.27) | 0 (0.00) |
| Non-Hodgkin's lymphoma | 0 (0.00) | 0 (0.00) | 1 (0.09) | 1 (0.12) |
| Adenocarcinoma of appendix | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| Glioblastoma | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| Ovarian cancer | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| Squamous cell carcinoma of the tongue | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| Vascular disorders | **8 (0.13)** | **5 (0.12)** | **4 (0.35)** | **1 (0.12)** |
| Deep vein thrombosis | 0 (0.00) | 0 (0.00) | 2 (0.18) | 0 (0.00) |
| Peripheral ischaemia | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.12) |

**Table 2.5-20: Incidence Rates of Serious Adverse Events Reported from After Start of First Vaccination Through the Respective Data Cutoff Dates of the Individual Clinical Trials with an Incidence Rate > 0.10 e/100 PY in the Pooled Analysis of Safety Data**

| System Organ Class/Preferred Term (MedDRA Version 23.1) | Participants 18 to ≤ 64 Years | | Participants ≥ 65 Years | |
|---|---|---|---|---|
| | NVX-CoV2373 N = 25282 | Placebo N = 16433 | NVX-CoV2373 N = 4776 | Placebo N = 3459 |
| **Blood and lymphatic system disorders** | **5 (0.08)** | **2 (0.05)** | **0 (0.00)** | **2 (0.25)** |
| Anaemia | 1 (0.02) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| Iron deficiency anaemia | 1 (0.02) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| **General disorders and administration site conditions** | **3 (0.05)** | **4 (0.10)** | **5 (0.44)** | **2 (0.25),** |
| Chest pain | 1 (0.02) | 2 (0.05) | 0 (0.00) | 1 (0.12) |
| Asthenia | 0 (0.00) | 0 (0.00) | 2 (0.18) | 0 (0.00) |
| Oedema | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| **Metabolism and nutrition disorders** | **3 (0.05)** | **8 (0.20)** | **1 (0.09)** | **1 (0.12)** |
| Hypoalbuminaemia | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| **Musculoskeletal and connective tissue disorders** | **3 (0.05)** | **3 (0.07)** | **3 (0.27)** | **0 (0.00)** |
| **Renal and urinary disorders** | **2 (0.03)** | **6 (0.15)** | **4 (0.35)** | **2 (0.25)** |
| Acute kidney injury | 1 (0.02) | 1 (0.02) | 2 (0.18) | 1 (0.12) |
| Renal failure | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| **Reproductive system and breast disorders** | **2 (0.03)** | **0 (0.00)** | **1 (0.09)** | **1 (0.12)** |
| Benign prostatic hyperplasia | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| **Surgical and medical procedures** | **2 (0.03)** | **1 (0.02)** | **0 (0.00)** | **1 (0.12)** |
| Spinal fusion surgery | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.12) |
| **Investigations** | **0 (0.00)** | **2 (0.05)** | **0 (0.00)** | **1 (0.12)** |
| Blood pressure systolic increased | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.12) |

Abbreviations: e/100 PY = events per 100 person-years; MedDRA = Medical Dictionary for Regulatory Activities; SAE = serious adverse event; 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.

1. One event of prostate cancer in the older age cohort was censored from the pooled analysis of safety data because the event occurred after the unblinding date (this event was included in the 2019nCoV-301 Interim Report).

Note: Results are presented as number of events per 100 person-years, with the event rate in parentheses.
Source: T28.1.1, T28.1.2

### 2.5.6.7.8 Potential Immune-Mediated Medical Conditions

For the pooled analysis of safety data, the IRs of PIMMCs were evaluated based on 3 separate criteria: 1) protocol-defined Medical Dictionary for Regulatory Activities (MedDRA) preferred terms; 2) site-entered criteria on the case report forms; and 3) a combination of site-entered criteria and protocol-defined MedDRA preferred terms.

Table 2.5-21 summarizes the IRs of PIMMCs based on protocol-defined MedDRA preferred terms or site-entered criteria on the case report form reported from after the start of first vaccination through the respective data cutoff dates for each individual study. Overall IRs of

PIMMCs by site-entered criteria alone were 0.36 and 0.18 e/100 PY (Table 32 of the pooled analysis tables) for the NVX-CoV2373 and placebo groups, respectively; by protocol-defined MedDRA preferred terms, 0.40 and 0.39 e/100 PY (Table 37 of the pooled analysis tables), respectively; and by both site-entered criteria and protocol-defined MedDRA preferred terms, 0.55 and 0.43 e/100 PY (Table 42 of the pooled analysis tables). For the combined analysis, the IR of PIMMCs was numerically higher in the NVX-CoV2373 group than in the placebo group among participants 18 to ≤ 64 years of age but numerically lower than in the placebo group among participants ≥ 65 years of age. In the younger age cohort, there were no PIMMCs with an IR > 0.10 e/100 PY in either the NVX-CoV2373 or placebo group. In the older age cohort, there were no PIMMCs with an IR > 0.10 e/100 PY in the NVX-CoV2373 group compared with neuropathy peripheral (0.25) in the placebo group.

**Table 2.5-21: Incidence Rates of Potential Immune-Mediated Medical Conditions Based on Protocol-Defined MedDRA Preferred Terms or Site Entered Criteria on the Case Report Form from After Start of First Vaccination Through the Respective Data Cutoff Dates of the Individual Clinical Trials in the Pooled Analysis of Safety Data**

| System Organ Class/Preferred Term (MedDRA Version 23.1) | Participants 18 to ≤ 64 Years | | Participants ≥ 65 Years | |
|---|---|---|---|---|
| | NVX-CoV2373 N = 25282 | Placebo N = 16433 | NVX-CoV2373 N = 4776 | Placebo N = 3459 |
| **Total follow-up time (person-year)** | **6337.9** | **4074.4** | **1127.1** | **802.8** |
| **Median follow-up time after first vaccination (days)** | **93** | **92** | **91** | **88** |
| **Any PIMMC** | **36 (0.57)** | **16 (0.39)** | **5 (0.44)** | **5 (0.62)** |
| **Nervous system disorders** | **12 (0.19)** | **6 (0.15)** | **1 (0.09)** | **2 (0.25)** |
| Seizure | 4 (0.06) | 3 (0.07) | 0 | 0 |
| Neuropathy peripheral | 3 (0.05) | 0 | 0 | 2 (0.25) |
| Central nervous system inflammation | 1 (0.02) | 0 | 0 | 0 |
| Facial paralysis | 1 (0.02) | 1 (0.02) | 0 | 0 |
| Hypoaesthesia | 1 (0.02) | 1 (0.02) | 0 | 0 |
| Narcolepsy | 1 (0.02) | 0 | 0 | 0 |
| Peroneal nerve palsy | 1 (0.02) | 0 | 0 | 0 |
| Multiple sclerosis | 0 | 1 (0.02) | 0 | 0 |
| Neuralgia | 0 | 0 | 1 (0.09) | 0 |
| **Skin and subcutaneous tissue disorders** | **6 (0.09)** | **2 (0.05)** | **0** | **0** |
| Alopecia areata | 2 (0.03) | 0 | 0 | 0 |
| Psoriasis | 2 (0.03) | 0 | 0 | 0 |
| Erythema nodosum | 1 (0.02) | 0 | 0 | 0 |
| Pemphigoid | 1 (0.02) | 0 | 0 | 0 |
| Lichen planus | 0 | 1 (0.02) | 0 | 0 |
| Lichenoid keratosis | 0 | 1 (0.02) | 0 | 0 |

**Table 2.5-21: Incidence Rates of Potential Immune-Mediated Medical Conditions Based on Protocol-Defined MedDRA Preferred Terms or Site Entered Criteria on the Case Report Form from After Start of First Vaccination Through the Respective Data Cutoff Dates of the Individual Clinical Trials in the Pooled Analysis of Safety Data**

| System Organ Class/Preferred Term (MedDRA Version 23.1) | Participants 18 to ≤ 64 Years | | Participants ≥ 65 Years | |
|---|---|---|---|---|
| | NVX-CoV2373 N = 25282 | Placebo N = 16433 | NVX-CoV2373 N = 4776 | Placebo N = 3459 |
| **Musculoskeletal and connective tissue disorders** | **5 (0.08)** | **3 (0.07)** | **2 (0.18)** | **2 (0.25)** |
| Arthritis | 2 (0.03) | 0 | 0 | 0 |
| Polymyalgia rheumatica | 1 (0.02) | 0 | 1 (0.09) | 1 (0.12) |
| Psoriatic arthropathy | 1 (0.02) | 0 | 0 | 0 |
| Rheumatoid arthritis | 1 (0.02) | 2 (0.05) | 1 (0.09) | 1 (0.12) |
| Arthritis reactive | 0 | 1 (0.02) | 0 | 0 |
| **Eye disorders** | **4 (0.06)** | **1 (0.02)** | **0** | **0** |
| Uveitis | 3 (0.05) | 1 (0.02) | 0 | 0 |
| Iridocyclitis | 1 (0.02) | 0 (0.00) | 0 | 0 |
| **Endocrine disorders** | **3 (0.05)** | **1 (0.02)** | **1 (0.09)** | **0** |
| Autoimmune thyroiditis | 1 (0.02) | 1 (0.02) | 0 | 0 |
| Basedow's disease | 1 (0.02) | 0 | 1 (0.09) | 0 |
| Hyperthyroidism | 1 (0.02) | 0 | 0 | 0 |
| **Blood and lymphatic system disorders** | **2 (0.03)** | **1 (0.02)** | **0** | **1 (0.12)** |
| Thrombocytopenia | 2 (0.03) | 1 (0.02) | 0 | 1 (0.12) |
| **Cardiac disorders** | **1 (0.02)** | **0** | **0** | **0** |
| Myocarditis | 1 (0.02) | 0 | 0 | 0 |
| **Gastrointestinal disorders** | **1 (0.02)** | **2 (0.05)** | **1 (0.09)** | **0** |
| Crohn's disease | 1 (0.02) | 1 (0.02) | 0 | 0 |
| Coeliac disease | 0 | 1 (0.02) | 0 | 0 |
| Colitis ulcerative | 0 | 0 | 1 (0.09) | 0 |
| **Injury, poisoning and procedural complications** | **1 (0.02)** | **0** | **0** | **0** |
| Chillblains | 1 (0.02) | 0 | 0 | 0 |
| **Investigations** | **1 (0.02)** | **0** | **0** | **0** |
| Heparin-induced thrombocytopenia test | 1 (0.02) | 0 | 0 | 0 |

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities; NVX-CoV2373 = 5 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant; PIMMC = potential immune-mediated medical condition; SARS-CoV-2 rS = severe acute respiratory syndrome coronavirus 2 recombinant spike protein nanoparticle vaccine.

Note: Results are presented as number of events per 100 person-years, with the event rate in parentheses.

Source: T46.1.1, T46.1.2



## 2.5.6.8 Worldwide Marketing Experience

Not applicable; SARS-CoV-2 rS with Matrix-M adjuvant has not yet been approved for marketing in any country.

### 2.5.6.9 Safety Conclusions

A two-dose regimen of NVX-CoV2373 (5 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant), administered 21 days (+ 7 days) apart, was well tolerated with no safety concerns in adult participants ≥ 18 years of age with over 96% of participants receiving both doses of NVX-CoV2373.

- As expected, there were higher frequencies of solicited local and systemic TEAEs in the NVX-CoV2373 group than in the placebo group, especially after the second dose, the majority of solicited local TEAEs were of grade 1 or grade 2 severity and of short duration (median duration ≤ 2.0 days for local events and ≤ 1 day for systemic events).
- Frequencies of grade 3 solicited local and systemic TEAEs were relatively low but tended to occur at a higher frequency in the NVX-CoV2373 than in the placebo group. Relatively few participants reported grade 4 solicited local or systemic TEAEs.
- Tenderness and pain were the most frequent solicited local TEAEs and fatigue, muscle pain, and headache were the most frequent solicited systemic TEAEs.
- Overall, the safety profile of NVX-CoV2373 was similar to that seen with placebo, with higher frequencies of unsolicited TEAEs and treatment-related TEAEs in the NVX-CoV2373 group, primarily with events consistent with a reactogenic response.
- The majority of participants in the 2 treatment groups reported unsolicited TEAEs that were mild in severity.
- Fatal events occurred infrequently and equally between the study groups, with a frequency of 0.04%. No fatal event was assessed as related to NVX-CoV2373, and the events reported were mostly consistent with the morbidity associated with age and underlying medical conditions in the study population.
- No specific treatment-related TEAEs led to study discontinuation in either group.
- SAEs were infrequently reported and generally balanced between the treatment groups; although SAEs of Hepatobiliary Disorders were reported only in the NVX-CoV2373 group in participants 18 to 64 years of age, all of these events were assessed by the investigator or sponsor as not related to treatment.
- MAAEs and severe MAAEs were also balanced between the study groups.
- PIMMCs were numerically higher in the NVX-CoV2373 group than in the placebo group in participants 18 to 64 years of age but numerically lower in the NVX-CoV2373 than in the placebo group in participants ≥ 65 years of age.

# 2.5.7 BENEFITS AND RISKS CONCLUSIONS

## 2.5.7.1 Disease or Condition

In summary, Novavax is developing the SARS-CoV-2 rS vaccine with Matrix-M adjuvant for the proposed indication of active immunization for the prevention of COVID-19 caused by SARS-CoV-2 as described in Section 2.5.1.2. SARS-CoV-2 rS (5 µg per dose) with Matrix-M adjuvant (50 µg per dose) is intended for IM administration (0.5 mL) on Days 0 and 21 (+ 7 days) in humans. The SARS-CoV-2 rS vaccine candidate selected by Novavax features targeted mutations to improve resistance to proteolytic cleavage and enhance retention of the prefusion conformation. It binds to the hACE2 receptor with high affinity and exhibits good thermostability.

The COVID-19 pandemic is due to infection caused by the novel SARS-CoV-2 virus, which is the causative agent of a potentially fatal disease that is of great global public health concern. SARS-CoV-2 virus primarily impacts the lower respiratory tract with the spectrum of symptoms ranging from asymptomatic infections to mild respiratory symptoms to the lethal form of COVID-19 which is associated with severe pneumonia, acute respiratory distress, and fatality.

There are 2 main processes that appear to drive the pathogenesis of COVID-19 [NIH 2021]. Initially, the disease is primarily driven by the replication of SARS-CoV-2, then the disease appears to be driven by a dysregulated immune/inflammatory response to SARS-CoV-2 that leads to tissue damage. Based on this understanding, it is anticipated that therapies that directly target SARS-CoV-2 would have the greatest effect early in the course of the disease, while immunosuppressive/anti-inflammatory therapies are likely to be more beneficial in the later stages of COVID-19.

The clinical spectrum of SARS-CoV-2 infection includes asymptomatic or presymptomatic infection and mild, moderate, severe, and critical illness [NIH 2021]. Current clinical management of COVID-19 consists of infection prevention and control measures and supportive care, including supplemental oxygen and mechanical ventilatory support when indicated. Currently, remdesivir, an antiviral agent, has been approved in multiple regions for the treatment of COVID-19 in adults and adolescents. Nonetheless, prevention of infection via vaccination is likely to be the most reliable means of providing protection from this disease. To date, several vaccines have been authorized in multiple countries globally for the prevention of COVID-19. Despite these preventative measures and treatments, there remains an unmet medical need. While multiple vaccines for the prevention of COVID-19 continue in development, the National Institutes of Health (NIH) has reported that more than one effective vaccine approach likely will be needed to successfully protect the global community from SARS-CoV-2, emphasizing that no single vaccine or vaccine platform is likely to meet the global need [NIH 2020]. Novavax's SARS-CoV-2 rS vaccine adjuvanted with Matrix-M is one such platform.

### 2.5.7.2 Benefits

The primary efficacy objectives of the pivotal Phase 3 Clinical Studies 2019nCoV-302 and 2019nCoV-301 were achieved, with the VEs of NVX-CoV2373 to prevent PCR-confirmed symptomatic mild, moderate, or severe COVID-19 shown to be 89.7% and 90.4%, respectively, after 106 and 77 cases, respectively, were accrued. The vaccine was also shown to be efficacious against non-B.1.1.7 variant strains in the UK (96.4%) in Clinical Study 2019nCoV-301 and variants that were either considered VOC/VOI (93.2%) or not considered VOC/VOI (100%) in Clinical Study 2019nCoV-301 and specifically against the B.1.1.7 (Alpha) variant (86.3% and 93.6%, in Clinical Studies 2019nCoV-301 and 2019nCoV-302, respectively). The vaccine was also observed to be efficacious in preventing moderate or severe COVID-19, with no NVX-CoV2373 recipient experiencing a severe event with an onset from at least 7 days after second vaccination (eg, Day 28). In a Phase 2a/b efficacy study, 2019nCoV-501, conducted in South Africa at the time when the B.1.351 (Beta) variant was prevalent, NVX-CoV2373 was efficacious in preventing PCR-confirmed symptomatic mild, moderate, or severe COVID-19 in both HIV-negative and HIV-positive participants with a VE of 48.6% (55.4% in HIV-negative participants). The participant populations of the Phase 3 studies included adult participants ≥ 18 years of age who, by virtue of age, race, ethnicity, or life circumstances were considered at substantial risk of exposure to and infection with SARS-CoV-2. Efforts were made to prioritize the enrollment of participants ≥ 65 years of age, participants < 65 years of age with co-morbidities (ie, obesity, chronic kidney or lung disease, cardiovascular disease, and diabetes mellitus type 2), who were at higher risk of complications due to COVID-19. Participants were also considered at high risk if their living or working conditions involved known frequent exposure to SARS-CoV-2 or to densely populated circumstances (factory or meat packing plants, essential retail workers, etc). In an exploratory endpoint of Clinical Study 2019nCoV-302, VE was 74.8% (95% CI: -19.7, 94.7) in a subset of approximately 400 participants who were co-administered a seasonal influenza vaccine at the first vaccination.

The immunogenicity of NVX-CoV2373 was evaluated in Clinical Studies 2019nCoV-101 (Part 1 and Part 2), 2019nCoV-501, and 2019nCoV-302 and was supportive of the efficacy of the vaccine in preventing PCR-confirmed symptomatic mild, moderate, or severe COVID-19 as demonstrated in the pivotal Phase 3 studies. In Clinical Study 2019nCoV-101 (Part 1 and Part 2), two-dose regimens of 5 µg and 25 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant generated robust immune responses (anti-S protein IgG and neutralizing antibody) including a relative skew toward $CD4^+$ T-cell responses of the Th1 phenotype, supporting the dose-sparing effect of Matrix-M adjuvant. In Clinical Study 2019nCoV-101 (Part 2), the two-dose regimen of 5 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant was better tolerated than the two-dose regimen of 25 µg SARS-CoV-2 rS with 50 µg Matrix-M adjuvant with generally comparable immune responses between the two antigen doses, and thus the lower dose was selected for use in later stage efficacy studies. Attenuation of immune response was observed among older participants, although SCRs were consistent between younger and older adults and efficacy estimates for both age groups were high, with VEs of 89.8% (95% CI: 79.7, 94.9) and 88.9% (95% CI: 20.2, 99.7), respectively, in Clinical Study 2019nCoV-302. In Clinical Study 2019nCoV-302, among a subset of participants

co-administered seasonal influenza vaccine, HAI immune response was not statistically significantly different between NVX-CoV2373 and placebo while the immune response for anti-S protein IgG, while lower, remained robust.

### 2.5.7.3 Risks

The safety of NVX-CoV2373 is based on the results of the individual studies conducted as well as on the pooled analysis of safety data across the SARS-CoV-2 rS clinical development program, comprising 28,963 recipients receiving at least 2 doses of vaccine. As expected, solicited local and systemic adverse reactions were more common in participants who received NVX-CoV2373 than placebo, especially after second vaccination. The majority of these reactions was mild or moderate in severity and resolved within 2 days. The overall frequency of unsolicited TEAEs was higher in the NVX-CoV2373 group than in the placebo across both age strata, with reactogenicity events such as fatigue, injection site pain, pyrexia, and myalgia extending beyond the 7-day post-injection window largely accounting for the differences between the 2 study groups. A total of 20 deaths occurred across the SARS-CoV-2 rS clinical program and were balanced across the NVX-CoV2373 and placebo groups (0.04% each). None of these events were assessed as related to treatment by both the investigator and sponsor. Causes of death were consistent with the participant populations enrolled in the studies. Incidence rates of SAEs were generally comparable across the NVX-CoV2373 and placebo groups with participants aged ≥ 65 years showing higher incidence rates in both active and placebo groups as may be expected (3.28 active vs 3.53 placebo in participants 18 to ≤ 64 years and 6.74 active vs 6.60 placebo in participants ≥ 65 years). Lastly, incidence rates of PIMMCs were overall comparable with slightly higher rates in participants 18 to ≤ 64 years receiving NVX-CoV2373 (0.57 active versus 0.39 placebo), while the opposite trend was observed in participants ≥ 65 years (0.44 active versus 0.62 placebo).

There were no cases of severe COVID-19 with an onset from at least 7 days after second vaccination among participants receiving NVX-CoV2373 and no evidence of vaccine-enhanced respiratory disease.

### 2.5.7.4 Benefit-Risk Assessment

It has been well over a year since SARS-CoV-2 has been declared a global pandemic by the World Health Organization (WHO). Several vaccines against the prototype Wuhan-Hu-1 strain have received authorizations globally as of late 2020/early 2021, with over 4 billion vaccine doses administered globally as of 09 August 2021 [WHO 2021a]. Despite this vaccination rate, there remains a large global need for additional vaccine doses, including vaccines efficacious against the evolving variants and having more readily satisfied storage conditions and stability. Based on the results of 2 pivotal Phase 3 studies, NVX-CoV2373 prevents PCR-confirmed symptomatic mild, moderate, or severe COVID-19 with observed efficacies of ~90%, with comparable efficacies against the against non B.1.1.7 variant strains (96.4%) and variants that were either considered VOC/VOI (93.2%) or not considered VOC/VOI (100%) and specifically against the B.1.1.7 (Alpha) variant (86.3% and 93.6%). Among NVX-CoV2373 recipients, there have been no cases of severe disease with an onset from at least 7 days after second vaccination, which mitigates concerns over vaccine-

enhanced respiratory disease. The clinical benefit of NVX-CoV2373 was consistent among younger and older adults, males and females, White and non-White, Black or African Americans, and those with co-morbidities or at high-risk of being exposed or infected with SARS-CoV-2.

The results of the pivotal efficacy studies both demonstrating ~90% efficacy against mild, moderate, or severe COVID-19, as well as 100% efficacy against severe disease, are supported by the robust immune responses observed in both early- and late-stage clinical studies. While attenuation of immune response was observed among older participants, SCRs and efficacy estimates were consistent between younger and older adults. NVX-CoV2373 also induced $CD4^+$ T cells that skewed toward a Th1 phenotype.

Based on the administration of NVX-CoV2373 to 30,058 adults across the SARS-CoV-2 rS clinical development program, there have been no safety concerns and the safety profile has been largely characterized by mild or moderate reactogenicity reactions of short duration (median duration of 1-2 days). Most common among these reactions were tenderness and pain at the injection site and systemic events of fatigue, muscle pain, and headache. Although the incidence of unsolicited TEAEs were slightly higher in the NVX-CoV2373 group than in the placebo group, the difference was largely due to reactogenicity-like events. SAEs and deaths occurred in few participants, with similar events for placebo and vaccine recipients that were generally balanced across treatment groups.

Based on the totality of the data across the SARS-CoV-2 rS clinical development program, NVX-CoV2373 administered as 2 IM injections at least 21 days (+ 7 days) apart is an effective vaccine with an acceptable safety profile for the active immunization for the prevention of COVID-19 caused by SARS-CoV-2. Considering the ongoing public health emergency due to SARS-CoV-2 and its emerging variants and the need for additional effective vaccine doses, along with the available efficacy, immunogenicity, and safety data across the SARS-CoV-2 rS clinical development program, the Sponsor considers that the known and potential benefits of the product outweigh the known and potential risks of NVX-CoV2373 and warrant consideration for authorization.

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## 2.5.9 TABLE OF CONTENTS FOR POOLED ANALYSIS OF SAFETY DATA

**Table 1 Summary of Clinical Trials and the Number of Participants Included in the Integrated Summary of Safety**

| Study Number (Country) | Study Design (Randomization ratio) | Treatment Groups (Dose 1 at Day 0 + Dose 2 at Day 21)<br>V = SARS-CoV-2 rS vaccine<br>M = Matrix-M1 adjuvant<br>P = Placebo | Number of Participants Included in the Integrated Summary of Safety | |
|---|---|---|---|---|
| | | | Vaccine SARS-CoV-2 rS (5µg) + Matrix-M1 adjuvant (50µg) | Placebo |
| 2019nCoV-101 - Part 1 (Australia) | Phase 1, randomized, observer-blinded, placebo-controlled in healthy adults >= 18 to <= 59 years of age (1:1:1:1:1) | A: P + P<br>B: V (25µg) and M (0µg) + V (25µg) and M (0µg)<br>C: V (5µg) and M (50µg) + V (5µg) and M (50µg)<br>D: V (25µg) and M (50µg) + V (25µg) and M (50µg)<br>E: V (25µg) and M (50µg) + P | 29 (Group C) | 23 (Group A) |
| 2019nCoV-101 - Part 2 (Australia and US) | Phase 2, randomized, observer-blinded, placebo-controlled in healthy adult subjects >= 18 to < 85 years of age (1:1:1:1:1) | A: P + P<br>B: V (5µg) and M (50µg) + V (5µg) and M (50µg)<br>C: V (5µg) and M (50µg) + P<br>D: V (25µg) and M (50µg) + V (25µg) and M (50µg)<br>E: V (25µg) and M (50µg) + P | 514 (Groups B and C) | 255 (Group A) |

**Table 1 Summary of Clinical Trials and the Number of Participants Included in the Integrated Summary of Safety**

| Study Number (Country) | Study Design (Randomization ratio) | Treatment Groups (Dose 1 at Day 0 + Dose 2 at Day 21) V = SARS-CoV-2 rS vaccine M = Matrix-M1 adjuvant P = Placebo | Number of Participants Included in the Integrated Summary of Safety | |
|---|---|---|---|---|
| | | | Vaccine SARS-CoV-2 rS (5µg) + Matrix-M1 adjuvant (50µg) | Placebo |
| 2019nCoV-501 (South Africa) | Phase 2a/2b, randomized, observer-blinded, placebo-controlled in healthy adult HIV-negative subjects and in medically stable adult HIV-positive subjects >= 18 to < 85 years of age (1:1) | A: P + P<br>B: V (5µg) and M (50µg) + V (5µg) and M (50µg) | 2,211 | 2,197 |
| 2019nCoV-302 (United Kingdom) | Phase 3, randomised, observer-blinded, placebo-controlled trial in adults 18 to 84 years (1:1) | A: P + P<br>B: V (5µg) and M (50µg) + V (5µg) and M (50µg) | 7,575 | 7,564 |

**Table 1 Summary of Clinical Trials and the Number of Participants Included in the Integrated Summary of Safety**

| Study Number (Country) | Study Design (Randomization ratio) | Treatment Groups (Dose 1 at Day 0 + Dose 2 at Day 21) V = SARS-CoV-2 rS vaccine M = Matrix-M1 adjuvant P = Placebo | Number of Participants Included in the Integrated Summary of Safety | |
|---|---|---|---|---|
| | | | Vaccine SARS-CoV-2 rS (5µg) + Matrix-M1 adjuvant (50µg) | Placebo |
| 2019nCoV-301 (US, Mexico) | Phase 3, randomized, observer-blinded, placebo-controlled Study to in adults >= 18 years of age (2:1) | A: P + P<br>B: V (5µg) and M (50µg) + V (5µg) and M (50µg) | 19,729 | 9,853 |
| Total | | | 30,058 | 19,892 |

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**Table 2 Summary of the Number of Participants Included In the Integrated Summary of Safety**

| | Number of Participants Included in the Safety Analysis | |
|---|---|---|
| Number of Doses Received | Vaccine SARS-CoV-2 rS (5µg) + Matrix-M1 adjuvant (50µg) | Placebo |
| Two doses | 28,963 | 19,270 |
| One dose* | 1,095* | 622 |
| Total | 30,058 | 19,892 |

*Participants receiving a mixed regimen are included in the ISS as receiving 1 dose of the active vaccine and only the data post the active vaccine dose are included in the analysis. They will not be included in the analysis of short-term safety post the second dose of the active vaccine

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**Table 3 Demographic Characteristics of Participants Included in the Integrated Summary of Safety**

| Demographic Characteristics | Vaccine (n, %) N = 30058 | Placebo (n, %) N = 19892 | Total N = 49950 |
|---|---|---|---|
| Age | | | |
| 18-64 | 25282 (84.11) | 16433 (82.61) | 41715 |
| >= 65 | 4776 (15.89) | 3459 (17.39) | 8235 |
| Gender | | | |
| Male | 15826 (52.65) | 10364 (52.10) | 26190 |
| Female | 14232 (47.35) | 9528 (47.90) | 23760 |
| Race | | | |
| White | 22415 (74.57) | 14808 (74.44) | 37223 |
| Black or African American | 4417 (14.69) | 3256 (16.37) | 7673 |
| Asian | 1119 (3.72) | 691 (3.47) | 1810 |
| American Indian or Alaska Native | 1322 (4.40) | 665 (3.34) | 1987 |
| Native Hawaiian or Other Pacific Islander | 58 (0.19) | 13 (0.07) | 71 |
| Multiple | 463 (1.54) | 260 (1.31) | 723 |
| Not Reported | 209 (0.70) | 134 (0.67) | 343 |
| Other | 43 (0.14) | 54 (0.27) | 97 |
| Missing | 12 (0.04) | 11 (0.06) | 23 |

**Table 3 Demographic Characteristics of Participants Included in the Integrated Summary of Safety**

| Demographic Characteristics | Vaccine (n, %) N = 30058 | Placebo (n, %) N = 19892 | Total N = 49950 |
|---|---|---|---|
| Ethnicity | | | |
| Hispanic/Latino | 4463 (14.85) | 2262 (11.37) | 6725 |
| Not Hispanic/Latino | 24647 (82.00) | 16747 (84.19) | 41394 |
| Not Reported | 780 (2.59) | 726 (3.65) | 1506 |
| Unknown | 161 (0.54) | 152 (0.76) | 313 |
| Missing | 7 (0.02) | 5 (0.03) | 12 |

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**Table 8.1.1_1.a Subgroup Summary of Local (Injection Site) Reactogenicity Adverse Events for Dose 1 (Day 0 to 6 Post Vaccination) By Age (18-64 Years)**

| | Vaccine (n, %, 95% CI) N = 19436 | Placebo (n, %, 95% CI) N = 11153 | Risk Difference (Vaccine - Placebo) (%, 95% CI) |
|---|---|---|---|
| Any solicited local reactogenicity AEs | 11192 (57.58), (56.89, 58.28) | 2296 (20.59), (19.84, 21.35) | 35.55 (34.53, 36.58) |
| Mild | 7762 (39.94) | 1840 (16.50) | |
| Moderate | 3200 (16.46) | 427 (3.83) | |
| Severe | 229 (1.18) | 28 (0.25) | |
| Potentially Life Threatening | 1 (<0.01) | 1 (<0.01) | |
| Pain | 6846 (35.22), (34.55, 35.90) | 1276 (11.44), (10.86, 12.05) | 23.40 (22.50, 24.30) |
| Mild | 6397 (32.91) | 1203 (10.79) | |
| Moderate | 374 (1.92) | 66 (0.59) | |
| Severe | 75 (0.39) | 7 (0.06) | |
| Potentially Life Threatening | 0 | 0 | |
| Tenderness | 9902 (50.95), (50.24, 51.65) | 1752 (15.71), (15.04, 16.40) | 33.38 (32.42, 34.34) |
| Mild | 6627 (34.10) | 1339 (12.01) | |
| Moderate | 3095 (15.92) | 393 (3.52) | |
| Severe | 179 (0.92) | 19 (0.17) | |
| Potentially Life Threatening | 1 (<0.01) | 1 (<0.01) | |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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**Table 8.1.1_1.a Subgroup Summary of Local (Injection Site) Reactogenicity Adverse Events for Dose 1 (Day 0 to 6 Post Vaccination) By Age (18-64 Years)**

| | Vaccine (n, %, 95% CI) N = 19436 | Placebo (n, %, 95% CI) N = 11153 | Risk Difference (Vaccine - Placebo) (%, 95% CI) |
|---|---|---|---|
| Erythema | 190 (0.98), (0.84, 1.13) | 32 (0.29), (0.20, 0.40) | 0.71 (0.54, 0.89) |
| Mild | 157 (0.81) | 26 (0.23) | |
| Moderate | 29 (0.15) | 5 (0.04) | |
| Severe | 4 (0.02) | 1 (<0.01) | |
| Potentially Life Threatening | 0 | 0 | |
| Swelling | 170 (0.87), (0.75, 1.02) | 35 (0.31), (0.22, 0.44) | 0.57 (0.40, 0.74) |
| Mild | 115 (0.59) | 20 (0.18) | |
| Moderate | 49 (0.25) | 11 (0.10) | |
| Severe | 6 (0.03) | 4 (0.04) | |
| Potentially Life Threatening | 0 | 0 | |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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**Table 8.1.1_2.a Subgroup Summary of Local (Injection Site) Reactogenicity Adverse Events for Dose 2 (Day 0 to 6 Post Vaccination) By Age (18-64 Years)**

| | Vaccine (n, %, 95% CI) N = 18340 | Placebo (n, %, 95% CI) N = 10488 | Risk Difference (Vaccine - Placebo) (%, 95% CI) |
|---|---|---|---|
| Any solicited local reactogenicity AEs | 13852 (75.53), (74.90, 76.15) | 2058 (19.62), (18.87, 20.40) | 53.12 (52.14, 54.10) |
| Mild | 6178 (33.69) | 1684 (16.06) | |
| Moderate | 6461 (35.23) | 341 (3.25) | |
| Severe | 1206 (6.58) | 32 (0.31) | |
| Potentially Life Threatening | 7 (0.04) | 1 (<0.01) | |
| Pain | 10570 (57.63), (56.91, 58.35) | 1320 (12.59), (11.96, 13.24) | 43.07 (42.11, 44.02) |
| Mild | 8029 (43.78) | 1217 (11.60) | |
| Moderate | 2196 (11.97) | 88 (0.84) | |
| Severe | 340 (1.85) | 14 (0.13) | |
| Potentially Life Threatening | 5 (0.03) | 1 (<0.01) | |
| Tenderness | 12731 (69.42), (68.74, 70.08) | 1501 (14.31), (13.65, 15.00) | 52.18 (51.26, 53.10) |
| Mild | 5643 (30.77) | 1196 (11.40) | |
| Moderate | 6197 (33.79) | 286 (2.73) | |
| Severe | 888 (4.84) | 19 (0.18) | |
| Potentially Life Threatening | 3 (0.02) | 0 | |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

File Name: t8_1_1_2_a.rtf. Generated from t_sol_sum_adhoc.sas 09AUG2021 14:14

**Table 8.1.1_2.a Subgroup Summary of Local (Injection Site) Reactogenicity Adverse Events for Dose 2 (Day 0 to 6 Post Vaccination) By Age (18-64 Years)**

| | Vaccine (n, %, 95% CI) N = 18340 | Placebo (n, %, 95% CI) N = 10488 | Risk Difference (Vaccine - Placebo) (%, 95% CI) |
|---|---|---|---|
| Erythema | 1162 (6.34), (5.99, 6.70) | 31 (0.30), (0.20, 0.42) | 5.82 (5.46, 6.18) |
| Mild | 467 (2.55) | 18 (0.17) | |
| Moderate | 547 (2.98) | 11 (0.10) | |
| Severe | 148 (0.81) | 2 (0.02) | |
| Potentially Life Threatening | 0 | 0 | |
| Swelling | 1066 (5.81), (5.48, 6.16) | 26 (0.25), (0.16, 0.36) | 5.39 (5.04, 5.74) |
| Mild | 551 (3.00) | 16 (0.15) | |
| Moderate | 427 (2.33) | 9 (0.09) | |
| Severe | 88 (0.48) | 1 (<0.01) | |
| Potentially Life Threatening | 0 | 0 | |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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**Table 8.1.2_1.a Subgroup Summary of Local (Injection Site) Reactogenicity Adverse Events for Dose 1 (Day 0 to 6 Post Vaccination) By Age (>= 65 Years)**

| | Vaccine (n, %, 95% CI) N = 2673 | Placebo (n, %, 95% CI) N = 1498 | Risk Difference (Vaccine - Placebo) (%, 95% CI) |
|---|---|---|---|
| Any solicited local reactogenicity AEs | 994 (37.19), (35.35, 39.05) | 216 (14.42), (12.68, 16.30) | 22.03 (19.46, 24.61) |
| Mild | 848 (31.72) | 175 (11.68) | |
| Moderate | 131 (4.90) | 38 (2.54) | |
| Severe | 15 (0.56) | 3 (0.20) | |
| Potentially Life Threatening | 0 | 0 | |
| Pain | 508 (19.00), (17.53, 20.54) | 114 (7.61), (6.32, 9.07) | 10.88 (8.88, 12.89) |
| Mild | 491 (18.37) | 111 (7.41) | |
| Moderate | 13 (0.49) | 2 (0.13) | |
| Severe | 4 (0.15) | 1 (0.07) | |
| Potentially Life Threatening | 0 | 0 | |
| Tenderness | 880 (32.92), (31.14, 34.74) | 170 (11.35), (9.79, 13.06) | 20.95 (18.53, 23.38) |
| Mild | 752 (28.13) | 132 (8.81) | |
| Moderate | 117 (4.38) | 36 (2.40) | |
| Severe | 11 (0.41) | 2 (0.13) | |
| Potentially Life Threatening | 0 | 0 | |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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**Table 8.1.2_1.a Subgroup Summary of Local (Injection Site) Reactogenicity Adverse Events for Dose 1 (Day 0 to 6 Post Vaccination) By Age (>= 65 Years)**

| | Vaccine (n, %, 95% CI) N = 2673 | Placebo (n, %, 95% CI) N = 1498 | Risk Difference (Vaccine - Placebo) (%, 95% CI) |
|---|---|---|---|
| Erythema | 20 (0.75), (0.46, 1.15) | 5 (0.33), (0.11, 0.78) | 0.40 (-0.05, 0.86) |
| Mild | 17 (0.64) | 4 (0.27) | |
| Moderate | 3 (0.11) | 1 (0.07) | |
| Severe | 0 | 0 | |
| Potentially Life Threatening | 0 | 0 | |
| Swelling | 18 (0.67), (0.40, 1.06) | 1 (0.07), (0.00, 0.37) | 0.56 (0.24, 0.88) |
| Mild | 10 (0.37) | 1 (0.07) | |
| Moderate | 7 (0.26) | 0 | |
| Severe | 1 (0.04) | 0 | |
| Potentially Life Threatening | 0 | 0 | |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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**Table 8.1.2_2.a Subgroup Summary of Local (Injection Site) Reactogenicity Adverse Events for Dose 2 (Day 0 to 6 Post Vaccination) By Age (>= 65 Years)**

| | Vaccine (n, %, 95% CI) N = 2392 | Placebo (n, %, 95% CI) N = 1346 | Risk Difference (Vaccine - Placebo) (%, 95% CI) |
|---|---|---|---|
| Any solicited local reactogenicity AEs | 1448 (60.54), (58.54, 62.50) | 188 (13.97), (12.16, 15.93) | 45.32 (42.60, 48.04) |
| Mild | 935 (39.09) | 151 (11.22) | |
| Moderate | 451 (18.85) | 34 (2.53) | |
| Severe | 62 (2.59) | 3 (0.22) | |
| Potentially Life Threatening | 0 | 0 | |
| Pain | 976 (40.80), (38.82, 42.80) | 122 (9.06), (7.58, 10.73) | 30.26 (27.73, 32.78) |
| Mild | 865 (36.16) | 119 (8.84) | |
| Moderate | 97 (4.06) | 2 (0.15) | |
| Severe | 14 (0.59) | 1 (0.07) | |
| Potentially Life Threatening | 0 | 0 | |
| Tenderness | 1324 (55.35), (53.33, 57.36) | 127 (9.44), (7.93, 11.12) | 45.05 (42.51, 47.59) |
| Mild | 892 (37.29) | 96 (7.13) | |
| Moderate | 397 (16.60) | 30 (2.23) | |
| Severe | 35 (1.46) | 1 (0.07) | |
| Potentially Life Threatening | 0 | 0 | |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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**Table 8.1.2_2.a Subgroup Summary of Local (Injection Site) Reactogenicity Adverse Events for Dose 2 (Day 0 to 6 Post Vaccination) By Age (>= 65 Years)**

| | Vaccine (n, %, 95% CI) N = 2392 | Placebo (n, %, 95% CI) N = 1346 | Risk Difference (Vaccine - Placebo) (%, 95% CI) |
|---|---|---|---|
| Erythema | 125 (5.23), (4.37, 6.19) | 4 (0.30), (0.08, 0.76) | 5.00 (4.03, 5.97) |
| Mild | 45 (1.88) | 1 (0.07) | |
| Moderate | 71 (2.97) | 3 (0.22) | |
| Severe | 9 (0.38) | 0 | |
| Potentially Life Threatening | 0 | 0 | |
| Swelling | 139 (5.81), (4.91, 6.82) | 7 (0.52), (0.21, 1.07) | 5.39 (4.35, 6.42) |
| Mild | 62 (2.59) | 5 (0.37) | |
| Moderate | 67 (2.80) | 1 (0.07) | |
| Severe | 10 (0.42) | 1 (0.07) | |
| Potentially Life Threatening | 0 | 0 | |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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**Table 9.1.1_1.a Subgroup Summary of Systemic Reactogenicity Adverse Events for Dose 1 (Day 0 to 6 Post Vaccination) By Age (18-64 Years)**

| | Vaccine (n, %, 95% CI) N = 19436 | Placebo (n, %, 95% CI) N = 11153 | Risk Difference (Vaccine - Placebo) (%, 95% CI) |
|---|---|---|---|
| Any solicited systemic reactogenicity AEs | 9239 (47.54), (46.83, 48.24) | 4240 (38.02), (37.11, 38.93) | 8.06 (6.91, 9.20) |
| Mild | 5424 (27.91) | 2479 (22.23) | |
| Moderate | 3332 (17.14) | 1521 (13.64) | |
| Severe | 466 (2.40) | 234 (2.10) | |
| Potentially Life Threatening | 17 (0.09) | 6 (0.05) | |
| Fever | 121 (0.62), (0.52, 0.74) | 78 (0.70), (0.55, 0.87) | 0.06 (-0.13, 0.25) |
| Mild | 60 (0.31) | 41 (0.37) | |
| Moderate | 36 (0.19) | 21 (0.19) | |
| Severe | 19 (0.10) | 14 (0.13) | |
| Potentially Life Threatening | 6 (0.03) | 2 (0.02) | |
| Malaise | 2776 (14.28), (13.79, 14.78) | 1202 (10.78), (10.21, 11.37) | 2.86 (2.10, 3.62) |
| Mild | 1504 (7.74) | 654 (5.86) | |
| Moderate | 1119 (5.76) | 485 (4.35) | |
| Severe | 145 (0.75) | 61 (0.55) | |
| Potentially Life Threatening | 8 (0.04) | 2 (0.02) | |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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**Table 9.1.1_1.a Subgroup Summary of Systemic Reactogenicity Adverse Events for Dose 1 (Day 0 to 6 Post Vaccination) By Age (18-64 Years)**

| | Vaccine (n, %, 95% CI) N = 19436 | Placebo (n, %, 95% CI) N = 11153 | Risk Difference (Vaccine - Placebo) (%, 95% CI) |
|---|---|---|---|
| Fatigue | 4855 (24.98), (24.37, 25.59) | 2278 (20.42), (19.68, 21.19) | 3.29 (2.32, 4.26) |
| Mild | 2414 (12.42) | 1141 (10.23) | |
| Moderate | 2202 (11.33) | 1022 (9.16) | |
| Severe | 235 (1.21) | 114 (1.02) | |
| Potentially Life Threatening | 4 (0.02) | 1 (<0.01) | |
| Joint Pain | 1546 (7.95), (7.58, 8.34) | 736 (6.60), (6.15, 7.08) | 1.36 (0.76, 1.96) |
| Mild | 970 (4.99) | 470 (4.21) | |
| Moderate | 509 (2.62) | 236 (2.12) | |
| Severe | 65 (0.33) | 30 (0.27) | |
| Potentially Life Threatening | 2 (0.01) | 0 | |
| Muscle Pain | 4426 (22.77), (22.18, 23.37) | 1419 (12.72), (12.11, 13.36) | 9.38 (8.53, 10.24) |
| Mild | 3264 (16.79) | 1015 (9.10) | |
| Moderate | 1058 (5.44) | 361 (3.24) | |
| Severe | 101 (0.52) | 41 (0.37) | |
| Potentially Life Threatening | 3 (0.02) | 2 (0.02) | |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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**Table 9.1.1_1.a Subgroup Summary of Systemic Reactogenicity Adverse Events for Dose 1 (Day 0 to 6 Post Vaccination) By Age (18-64 Years)**

| | Vaccine (n, %, 95% CI) N = 19436 | Placebo (n, %, 95% CI) N = 11153 | Risk Difference (Vaccine - Placebo) (%, 95% CI) |
|---|---|---|---|
| Headache | 4906 (25.24), (24.63, 25.86) | 2486 (22.29), (21.52, 23.07) | 2.32 (1.33, 3.32) |
| Mild | 3707 (19.07) | 1896 (17.00) | |
| Moderate | 1037 (5.34) | 507 (4.55) | |
| Severe | 157 (0.81) | 82 (0.74) | |
| Potentially Life Threatening | 5 (0.03) | 1 (<0.01) | |
| Nausea or Vomiting | 1284 (6.61), (6.26, 6.96) | 638 (5.72), (5.30, 6.17) | 0.82 (0.26, 1.38) |
| Mild | 1014 (5.22) | 495 (4.44) | |
| Moderate | 243 (1.25) | 126 (1.13) | |
| Severe | 22 (0.11) | 14 (0.13) | |
| Potentially Life Threatening | 5 (0.03) | 3 (0.03) | |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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**Table 9.1.1_2.a Subgroup Summary of Systemic Reactogenicity Adverse Events for Dose 2 (Day 0 to 6 Post Vaccination) By Age (18-64 Years)**

| | Vaccine (n, %, 95% CI) N = 18340 | Placebo (n, %, 95% CI) N = 10488 | Risk Difference (Vaccine - Placebo) (%, 95% CI) |
|---|---|---|---|
| Any solicited systemic reactogenicity AEs | 12205 (66.55), (65.86, 67.23) | 3427 (32.68), (31.78, 33.58) | 30.79 (29.67, 31.91) |
| Mild | 4230 (23.06) | 1860 (17.73) | |
| Moderate | 5826 (31.77) | 1345 (12.82) | |
| Severe | 2129 (11.61) | 216 (2.06) | |
| Potentially Life Threatening | 20 (0.11) | 6 (0.06) | |
| Fever | 1046 (5.70), (5.37, 6.05) | 49 (0.47), (0.35, 0.62) | 5.09 (4.75, 5.44) |
| Mild | 683 (3.72) | 29 (0.28) | |
| Moderate | 287 (1.56) | 10 (0.10) | |
| Severe | 73 (0.40) | 9 (0.09) | |
| Potentially Life Threatening | 3 (0.02) | 1 (<0.01) | |
| Malaise | 6766 (36.89), (36.19, 37.60) | 1119 (10.67), (10.08, 11.28) | 24.15 (23.25, 25.05) |
| Mild | 2088 (11.38) | 551 (5.25) | |
| Moderate | 3584 (19.54) | 499 (4.76) | |
| Severe | 1085 (5.92) | 67 (0.64) | |
| Potentially Life Threatening | 9 (0.05) | 2 (0.02) | |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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**Table 9.1.1_2.a Subgroup Summary of Systemic Reactogenicity Adverse Events for Dose 2 (Day 0 to 6 Post Vaccination) By Age (18-64 Years)**

| | Vaccine (n, %, 95% CI) N = 18340 | Placebo (n, %, 95% CI) N = 10488 | Risk Difference (Vaccine - Placebo) (%, 95% CI) |
|---|---|---|---|
| Fatigue | 8592 (46.85), (46.12, 47.57) | 1991 (18.98), (18.24, 19.75) | 25.09 (24.06, 26.11) |
| Mild | 2539 (13.84) | 934 (8.91) | |
| Moderate | 4624 (25.21) | 935 (8.91) | |
| Severe | 1425 (7.77) | 119 (1.13) | |
| Potentially Life Threatening | 4 (0.02) | 3 (0.03) | |
| Joint Pain | 3932 (21.44), (20.85, 22.04) | 670 (6.39), (5.93, 6.87) | 14.18 (13.43, 14.93) |
| Mild | 1688 (9.20) | 425 (4.05) | |
| Moderate | 1799 (9.81) | 212 (2.02) | |
| Severe | 440 (2.40) | 31 (0.30) | |
| Potentially Life Threatening | 5 (0.03) | 2 (0.02) | |
| Muscle Pain | 8440 (46.02), (45.30, 46.74) | 1120 (10.68), (10.09, 11.29) | 33.10 (32.19, 34.02) |
| Mild | 3870 (21.10) | 758 (7.23) | |
| Moderate | 3695 (20.15) | 315 (3.00) | |
| Severe | 870 (4.74) | 43 (0.41) | |
| Potentially Life Threatening | 5 (0.03) | 4 (0.04) | |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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**Table 9.1.1_2.a Subgroup Summary of Systemic Reactogenicity Adverse Events for Dose 2 (Day 0 to 6 Post Vaccination) By Age (18-64 Years)**

| | Vaccine (n, %, 95% CI) N = 18340 | Placebo (n, %, 95% CI) N = 10488 | Risk Difference (Vaccine - Placebo) (%, 95% CI) |
|---|---|---|---|
| Headache | 7932 (43.25), (42.53, 43.97) | 1930 (18.40), (17.66, 19.16) | 22.94 (21.92, 23.97) |
| Mild | 4232 (23.08) | 1388 (13.23) | |
| Moderate | 3140 (17.12) | 476 (4.54) | |
| Severe | 555 (3.03) | 64 (0.61) | |
| Potentially Life Threatening | 5 (0.03) | 2 (0.02) | |
| Nausea or Vomiting | 2068 (11.28), (10.82, 11.74) | 542 (5.17), (4.75, 5.61) | 5.71 (5.09, 6.34) |
| Mild | 1477 (8.05) | 408 (3.89) | |
| Moderate | 545 (2.97) | 119 (1.13) | |
| Severe | 39 (0.21) | 13 (0.12) | |
| Potentially Life Threatening | 7 (0.04) | 2 (0.02) | |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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**Table 9.1.2_1.a Subgroup Summary of Systemic Reactogenicity Adverse Events for Dose 1 (Day 0 to 6 Post Vaccination) By Age (>= 65 Years)**

| | Vaccine (n, %, 95% CI) N = 2673 | Placebo (n, %, 95% CI) N = 1498 | Risk Difference (Vaccine - Placebo) (%, 95% CI) |
|---|---|---|---|
| Any solicited systemic reactogenicity AEs | 850 (31.80), (30.04, 33.60) | 445 (29.71), (27.40, 32.09) | 1.39 (-1.55, 4.32) |
| Mild | 557 (20.84) | 281 (18.76) | |
| Moderate | 250 (9.35) | 149 (9.95) | |
| Severe | 41 (1.53) | 14 (0.93) | |
| Potentially Life Threatening | 2 (0.07) | 1 (0.07) | |
| Fever | 18 (0.67), (0.40, 1.06) | 12 (0.80), (0.41, 1.40) | 0.03 (-0.49, 0.56) |
| Mild | 8 (0.30) | 6 (0.40) | |
| Moderate | 7 (0.26) | 5 (0.33) | |
| Severe | 2 (0.07) | 1 (0.07) | |
| Potentially Life Threatening | 1 (0.04) | 0 | |
| Malaise | 263 (9.84), (8.74, 11.03) | 115 (7.68), (6.38, 9.14) | 1.73 (-0.06, 3.51) |
| Mild | 147 (5.50) | 59 (3.94) | |
| Moderate | 101 (3.78) | 51 (3.40) | |
| Severe | 15 (0.56) | 4 (0.27) | |
| Potentially Life Threatening | 0 | 1 (0.07) | |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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**Table 9.1.2_1.a Subgroup Summary of Systemic Reactogenicity Adverse Events for Dose 1 (Day 0 to 6 Post Vaccination) By Age (>= 65 Years)**

| | Vaccine (n, %, 95% CI) N = 2673 | Placebo (n, %, 95% CI) N = 1498 | Risk Difference (Vaccine - Placebo) (%, 95% CI) |
|---|---|---|---|
| Fatigue | 434 (16.24), (14.86, 17.69) | 213 (14.22), (12.49, 16.09) | 1.18 (-1.09, 3.44) |
| Mild | 231 (8.64) | 110 (7.34) | |
| Moderate | 179 (6.70) | 98 (6.54) | |
| Severe | 24 (0.90) | 5 (0.33) | |
| Potentially Life Threatening | 0 | 0 | |
| Joint Pain | 165 (6.17), (5.29, 7.15) | 91 (6.07), (4.92, 7.41) | 0.06 (-1.47, 1.59) |
| Mild | 98 (3.67) | 52 (3.47) | |
| Moderate | 61 (2.28) | 34 (2.27) | |
| Severe | 6 (0.22) | 5 (0.33) | |
| Potentially Life Threatening | 0 | 0 | |
| Muscle Pain | 335 (12.53), (11.30, 13.85) | 150 (10.01), (8.54, 11.65) | 2.09 (0.09, 4.09) |
| Mild | 265 (9.91) | 106 (7.08) | |
| Moderate | 67 (2.51) | 40 (2.67) | |
| Severe | 3 (0.11) | 4 (0.27) | |
| Potentially Life Threatening | 0 | 0 | |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

File Name: t9_1_2_1a.rtf. Generated from t_sol_sum_adhoc.sas 09AUG2021 14:14

**Table 9.1.2_1.a Subgroup Summary of Systemic Reactogenicity Adverse Events for Dose 1 (Day 0 to 6 Post Vaccination) By Age (>= 65 Years)**

| | Vaccine (n, %, 95% CI) N = 2673 | Placebo (n, %, 95% CI) N = 1498 | Risk Difference (Vaccine - Placebo) (%, 95% CI) |
|---|---|---|---|
| Headache | 405 (15.15), (13.81, 16.57) | 226 (15.09), (13.31, 17.00) | -0.21 (-2.51, 2.08) |
| Mild | 344 (12.87) | 188 (12.55) | |
| Moderate | 47 (1.76) | 34 (2.27) | |
| Severe | 13 (0.49) | 4 (0.27) | |
| Potentially Life Threatening | 1 (0.04) | 0 | |
| Nausea or Vomiting | 99 (3.70), (3.02, 4.49) | 38 (2.54), (1.80, 3.47) | 1.13 (0.04, 2.22) |
| Mild | 83 (3.11) | 30 (2.00) | |
| Moderate | 16 (0.60) | 8 (0.53) | |
| Severe | 0 | 0 | |
| Potentially Life Threatening | 0 | 0 | |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

File Name: t9_1_2_1_a.rtf. Generated from t_sol_sum_adhoc.sas 09AUG2021 14:14

**Table 9.1.2_2.a Subgroup Summary of Systemic Reactogenicity Adverse Events for Dose 2 (Day 0 to 6 Post Vaccination) By Age (>= 65 Years)**

| | Vaccine (n, %, 95% CI) N = 2392 | Placebo (n, %, 95% CI) N = 1346 | Risk Difference (Vaccine - Placebo) (%, 95% CI) |
|---|---|---|---|
| Any solicited systemic reactogenicity AEs | 1129 (47.20), (45.18, 49.22) | 340 (25.26), (22.96, 27.67) | 20.75 (17.66, 23.85) |
| Mild | 570 (23.83) | 204 (15.16) | |
| Moderate | 463 (19.36) | 116 (8.62) | |
| Severe | 94 (3.93) | 20 (1.49) | |
| Potentially Life Threatening | 2 (0.08) | 0 | |
| Fever | 45 (1.88), (1.38, 2.51) | 12 (0.89), (0.46, 1.55) | 1.00 (0.27, 1.73) |
| Mild | 31 (1.30) | 9 (0.67) | |
| Moderate | 11 (0.46) | 1 (0.07) | |
| Severe | 3 (0.13) | 2 (0.15) | |
| Potentially Life Threatening | 0 | 0 | |
| Malaise | 504 (21.07), (19.45, 22.76) | 116 (8.62), (7.17, 10.25) | 11.65 (9.43, 13.87) |
| Mild | 212 (8.86) | 64 (4.75) | |
| Moderate | 251 (10.49) | 45 (3.34) | |
| Severe | 41 (1.71) | 7 (0.52) | |
| Potentially Life Threatening | 0 | 0 | |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

File Name: t9_1_2_2_a.rtf. Generated from t_sol_sum_adhoc.sas 09AUG2021 14:14

**Table 9.1.2_2.a Subgroup Summary of Systemic Reactogenicity Adverse Events for Dose 2 (Day 0 to 6 Post Vaccination) By Age (>= 65 Years)**

| | Vaccine (n, %, 95% CI) N = 2392 | Placebo (n, %, 95% CI) N = 1346 | Risk Difference (Vaccine - Placebo) (%, 95% CI) |
|---|---|---|---|
| Fatigue | 688 (28.76), (26.95, 30.62) | 187 (13.89), (12.09, 15.86) | 13.80 (11.18, 16.42) |
| Mild | 267 (11.16) | 90 (6.69) | |
| Moderate | 359 (15.01) | 83 (6.17) | |
| Severe | 62 (2.59) | 14 (1.04) | |
| Potentially Life Threatening | 0 | 0 | |
| Joint Pain | 301 (12.58), (11.28, 13.98) | 76 (5.65), (4.47, 7.02) | 6.38 (4.55, 8.21) |
| Mild | 157 (6.56) | 39 (2.90) | |
| Moderate | 124 (5.18) | 34 (2.53) | |
| Severe | 19 (0.79) | 3 (0.22) | |
| Potentially Life Threatening | 1 (0.04) | 0 | |
| Muscle Pain | 631 (26.38), (24.62, 28.19) | 123 (9.14), (7.65, 10.81) | 16.48 (14.12, 18.84) |
| Mild | 391 (16.35) | 80 (5.94) | |
| Moderate | 206 (8.61) | 40 (2.97) | |
| Severe | 34 (1.42) | 3 (0.22) | |
| Potentially Life Threatening | 0 | 0 | |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

File Name: t9_1_2_2a.rtf. Generated from t_sol_sum_adhoc.sas 09AUG2021 14:14

**Table 9.1.2_2.a Subgroup Summary of Systemic Reactogenicity Adverse Events for Dose 2 (Day 0 to 6 Post Vaccination) By Age (>= 65 Years)**

| | Vaccine (n, %, 95% CI) N = 2392 | Placebo (n, %, 95% CI) N = 1346 | Risk Difference (Vaccine - Placebo) (%, 95% CI) |
|---|---|---|---|
| Headache | 569 (23.79), (22.09, 25.55) | 172 (12.78), (11.04, 14.68) | 10.36 (7.85, 12.86) |
| Mild | 434 (18.14) | 141 (10.48) | |
| Moderate | 116 (4.85) | 28 (2.08) | |
| Severe | 18 (0.75) | 3 (0.22) | |
| Potentially Life Threatening | 1 (0.04) | 0 | |
| Nausea or Vomiting | 126 (5.27), (4.41, 6.24) | 42 (3.12), (2.26, 4.19) | 1.96 (0.63, 3.28) |
| Mild | 100 (4.18) | 35 (2.60) | |
| Moderate | 24 (1.00) | 7 (0.52) | |
| Severe | 2 (0.08) | 0 | |
| Potentially Life Threatening | 0 | 0 | |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

File Name: t9_1_2_2_a.rtf. Generated from t_sol_sum_adhoc.sas 09AUG2021 14:14

**Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Any unsolicited AEs | 4627 (18.30), (17.83, 18.78) | 2577 (15.68), (15.13, 16.25) | 4.87 (4.14, 5.60) |
| General disorders and administration site conditions | 1610 (6.37), (6.07, 6.68) | 544 (3.31), (3.04, 3.60) | 4.23 (3.81, 4.65) |
| Fatigue | 478 (1.89) | 227 (1.38) | 0.90 (0.65, 1.16) |
| Injection site pain | 425 (1.68) | 78 (0.47) | 1.54 (1.32, 1.75) |
| Pyrexia | 265 (1.05) | 57 (0.35) | 0.85 (0.68, 1.02) |
| Chills | 144 (0.57) | 19 (0.12) | 0.53 (0.41, 0.65) |
| Pain | 131 (0.52) | 40 (0.24) | 0.34 (0.21, 0.46) |
| Malaise | 111 (0.44) | 36 (0.22) | 0.29 (0.18, 0.41) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

File Name: t13_1_1.rtf. Generated from t_unsol_sum_sub.sas 18JUL2021 20:16

**Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Injection site erythema | 78 (0.31) | 13 (0.08) | 0.28 (0.19, 0.37) |
| Influenza like illness | 76 (0.30) | 34 (0.21) | 0.18 (0.08, 0.28) |
| Injection site pruritus | 67 (0.27) | 5 (0.03) | 0.25 (0.17, 0.32) |
| Injection site swelling | 66 (0.26) | 5 (0.03) | 0.28 (0.20, 0.35) |
| Vaccination site pain | 38 (0.15) | 7 (0.04) | 0.15 (0.08, 0.21) |
| Peripheral swelling | 27 (0.11) | 6 (0.04) | 0.09 (0.04, 0.15) |
| Axillary pain | 25 (0.10) | 4 (0.02) | 0.09 (0.04, 0.14) |
| Injection site bruising | 25 (0.10) | 10 (0.06) | 0.07 (0.01, 0.12) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t13_1_1.rtf. Generated from t_unsol_sum_sub.sas 18JUL2021 20:16

**Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Injection site rash | 17 (0.07) | 1 (<0.01) | 0.08 (0.04, 0.12) |
| Chest discomfort | 13 (0.05) | 10 (0.06) | 0.00 (-0.04, 0.05) |
| Injection site mass | 13 (0.05) | 1 (<0.01) | 0.06 (0.02, 0.09) |
| Feeling cold | 11 (0.04) | 2 (0.01) | 0.05 (0.01, 0.08) |
| Tenderness | 11 (0.04) | 2 (0.01) | 0.03 (0.00, 0.06) |
| Chest pain | 10 (0.04) | 10 (0.06) | -0.03 (-0.08, 0.02) |
| Oedema peripheral | 10 (0.04) | 2 (0.01) | 0.02 (-0.01, 0.05) |
| Asthenia | 8 (0.03) | 3 (0.02) | 0.01 (-0.02, 0.04) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

File Name: t13_1_1.rtf. Generated from t_unsol_sum_sub.sas 18JUL2021 20:16

**Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Feeling abnormal | 8 (0.03) | 2 (0.01) | 0.02 (-0.01, 0.05) |
| Injection site hypoaesthesia | 8 (0.03) | 2 (0.01) | 0.03 (-0.00, 0.06) |
| Injection site inflammation | 8 (0.03) | 0 (0.00) | 0.04 (0.01, 0.07) |
| Vaccination site pruritus | 8 (0.03) | 0 (0.00) | 0.04 (0.01, 0.07) |
| Injection site discomfort | 7 (0.03) | 2 (0.01) | 0.03 (-0.00, 0.06) |
| Injection site reaction | 7 (0.03) | 3 (0.02) | 0.02 (-0.02, 0.05) |
| Non-cardiac chest pain | 7 (0.03) | 6 (0.04) | 0.00 (-0.04, 0.04) |
| Feeling hot | 6 (0.02) | 3 (0.02) | 0.01 (-0.02, 0.04) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t13_1_1.rtf. Generated from t_unsol_sum_sub.sas 18JUL2021 20:16

**Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Inflammation | 6 (0.02) | 2 (0.01) | 0.02 (-0.01, 0.05) |
| Injection site haemorrhage | 6 (0.02) | 1 (<0.01) | 0.02 (-0.00, 0.04) |
| Swelling | 6 (0.02) | 1 (<0.01) | 0.02 (-0.00, 0.04) |
| Injection site induration | 5 (0.02) | 1 (<0.01) | 0.01 (-0.01, 0.04) |
| Injection site scab | 5 (0.02) | 0 (0.00) | 0.03 (0.00, 0.05) |
| Injection site warmth | 5 (0.02) | 0 (0.00) | 0.02 (0.00, 0.05) |
| Vaccination site reaction | 5 (0.02) | 0 (0.00) | 0.02 (0.00, 0.04) |
| Vaccination site swelling | 5 (0.02) | 1 (<0.01) | 0.02 (-0.00, 0.04) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t13_1_1.rtf. Generated from t_unsol_sum_sub.sas 18JUL2021 20:16

**Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Feeling of body temperature change | 4 (0.02) | 1 (<0.01) | 0.02 (-0.01, 0.04) |
| Injection site discolouration | 4 (0.02) | 0 (0.00) | 0.02 (0.00, 0.03) |
| Thirst | 4 (0.02) | 0 (0.00) | 0.02 (0.00, 0.04) |
| Vaccination site erythema | 4 (0.02) | 1 (<0.01) | 0.01 (-0.01, 0.04) |
| Vessel puncture site bruise | 4 (0.02) | 7 (0.04) | -0.02 (-0.06, 0.01) |
| Vessel puncture site haematoma | 4 (0.02) | 1 (<0.01) | 0.01 (-0.01, 0.03) |
| Drug withdrawal syndrome | 3 (0.01) | 1 (<0.01) | 0.00 (-0.01, 0.02) |
| Facial pain | 3 (0.01) | 1 (<0.01) | 0.01 (-0.01, 0.03) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t13_1_1.rtf. Generated from t_unsol_sum_sub.sas 18JUL2021 20:16

**Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Injection site scar | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Reactogenicity event | 3 (0.01) | 0 (0.00) | 0.02 (-0.00, 0.03) |
| Vaccination site bruising | 3 (0.01) | 0 (0.00) | 0.02 (-0.00, 0.03) |
| Vaccination site discomfort | 3 (0.01) | 0 (0.00) | 0.02 (-0.00, 0.03) |
| Vaccination site paraesthesia | 3 (0.01) | 1 (<0.01) | 0.01 (-0.01, 0.03) |
| Vaccination site scar | 3 (0.01) | 0 (0.00) | 0.02 (-0.00, 0.03) |
| Application site pain | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Exercise tolerance decreased | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

File Name: t13_1_1.rtf. Generated from t_unsol_sum_sub.sas 18JUL2021 20:16

**Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Illness | 2 (<0.01) | 1 (<0.01) | 0.00 (-0.02, 0.02) |
| Injection site nodule | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Injection site papule | 2 (<0.01) | 1 (<0.01) | 0.01 (-0.01, 0.02) |
| Injection site paraesthesia | 2 (<0.01) | 1 (<0.01) | 0.00 (-0.02, 0.02) |
| Injection site urticaria | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Injection site vesicles | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Mucosal dryness | 2 (<0.01) | 1 (<0.01) | 0.00 (-0.02, 0.02) |
| Swelling face | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

File Name: t13_1_1.rtf. Generated from t_unsol_sum_sub.sas 18JUL2021 20:16

**Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Vaccination site inflammation | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Vaccination site irritation | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Vaccination site joint pain | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Adverse drug reaction | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |
| Catheter site bruise | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Chronic fatigue syndrome | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Crepitations | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Crying | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t13_1_1.rtf. Generated from t_unsol_sum_sub.sas 18JUL2021 20:16

**Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Cyst | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |
| Discomfort | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Gait disturbance | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.01, 0.01) |
| Induration | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Injection site fibrosis | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Injection site haematoma | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Injection site nerve damage | 1 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.01) |
| Local reaction | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

File Name: t13_1_1.rtf. Generated from t_unsol_sum_sub.sas 18JUL2021 20:16

**Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Mass | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Medical device pain | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Nodule | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.01, 0.01) |
| Oedema | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Sensation of foreign body | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Sick building syndrome | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Vaccination site discolouration | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Vaccination site dryness | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

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|---|---|---|---|
| Vaccination site lymphadenopathy | 1 (<0.01) | 4 (0.02) | -0.02 (-0.04, 0.01) |
| Vaccination site rash | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Vaccination site urticaria | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Vaccination site warmth | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Vessel puncture site pain | 1 (<0.01) | 4 (0.02) | -0.02 (-0.04, 0.00) |
| Catheter site pain | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Hangover | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Hernia pain | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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|---|---|---|---|
| Hunger | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Injection site irritation | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Injection site joint pain | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Injection site lymphadenopathy | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Injection site pallor | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Injury associated with device | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Secretion discharge | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Systemic inflammatory response syndrome | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |

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|---|---|---|---|
| Temperature intolerance | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Ulcer | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Vessel puncture site thrombosis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Withdrawal syndrome | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Nervous system disorders | 1042 (4.12), (3.88, 4.37) | 607 (3.69), (3.41, 3.99) | 1.21 (0.82, 1.60) |
| Headache | 736 (2.91) | 390 (2.37) | 1.16 (0.84, 1.48) |
| Dizziness | 74 (0.29) | 51 (0.31) | 0.02 (-0.09, 0.14) |
| Lethargy | 61 (0.24) | 25 (0.15) | 0.18 (0.09, 0.27) |

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|---|---|---|---|
| Migraine | 31 (0.12) | 18 (0.11) | 0.03 (-0.03, 0.10) |
| Paraesthesia | 26 (0.10) | 15 (0.09) | 0.02 (-0.05, 0.08) |
| Anosmia | 24 (0.09) | 39 (0.24) | -0.12 (-0.20, -0.03) |
| Syncope | 23 (0.09) | 15 (0.09) | 0.00 (-0.06, 0.07) |
| Tension headache | 23 (0.09) | 14 (0.09) | -0.01 (-0.07, 0.05) |
| Ageusia | 18 (0.07) | 31 (0.19) | -0.09 (-0.16, -0.02) |
| Presyncope | 15 (0.06) | 9 (0.05) | 0.00 (-0.04, 0.05) |
| Hypoaesthesia | 13 (0.05) | 8 (0.05) | 0.00 (-0.04, 0.05) |

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|---|---|---|---|
| Dysgeusia | 9 (0.04) | 11 (0.07) | -0.03 (-0.07, 0.02) |
| Sciatica | 6 (0.02) | 4 (0.02) | 0.00 (-0.03, 0.03) |
| Tremor | 6 (0.02) | 4 (0.02) | 0.01 (-0.02, 0.03) |
| Neuralgia | 4 (0.02) | 1 (<0.01) | 0.01 (-0.01, 0.03) |
| Parosmia | 4 (0.02) | 0 (0.00) | 0.02 (0.00, 0.03) |
| Restless legs syndrome | 4 (0.02) | 1 (<0.01) | 0.01 (-0.01, 0.03) |
| Disturbance in attention | 3 (0.01) | 2 (0.01) | 0.00 (-0.02, 0.02) |
| Seizure | 3 (0.01) | 1 (<0.01) | 0.00 (-0.01, 0.02) |

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|---|---|---|---|
| Sinus headache | 3 (0.01) | 1 (<0.01) | 0.01 (-0.01, 0.03) |
| Carpal tunnel syndrome | 2 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.02) |
| Cerebrovascular accident | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Hyperaesthesia | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Hypersomnia | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Neuropathy peripheral | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Radiculopathy | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Alcoholic seizure | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

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|---|---|---|---|
| Allodynia | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Altered state of consciousness | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Amnesia | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Burning sensation | 1 (<0.01) | 3 (0.02) | -0.01 (-0.04, 0.01) |
| Central nervous system inflammation | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Cerebral congestion | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Cubital tunnel syndrome | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Diabetic neuropathy | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Dizziness postural | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.01, 0.01) |
| Dystonia | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Facial paralysis | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.01, 0.01) |
| Incoherent | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Ischaemic stroke | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Migraine with aura | 1 (<0.01) | 5 (0.03) | -0.02 (-0.05, 0.00) |
| Morton's neuralgia | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Muscle tension dysphonia | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Nerve compression | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.01, 0.01) |
| Peroneal nerve palsy | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Seizure anoxic | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Sleep paralysis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Somnolence | 1 (<0.01) | 3 (0.02) | -0.01 (-0.03, 0.01) |
| Taste disorder | 1 (<0.01) | 5 (0.03) | -0.03 (-0.06, 0.00) |
| Balance disorder | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Carotid artery stenosis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |

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|---|---|---|---|
| Cerebellar infarction | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Cluster headache | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Epilepsy | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Head discomfort | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Hemiparesis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Hemiplegic migraine | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Loss of consciousness | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Lumbar radiculopathy | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |

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|---|---|---|---|
| Mental impairment | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Nystagmus | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Transient ischaemic attack | 0 (0.00) | 2 (0.01) | -0.01 (-0.03, 0.00) |
| Visual field defect | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Musculoskeletal and connective tissue disorders | 988 (3.91), (3.67, 4.15) | 360 (2.19), (1.97, 2.43) | 2.50 (2.15, 2.85) |
| Myalgia | 399 (1.58) | 102 (0.62) | 1.33 (1.12, 1.54) |
| Pain in extremity | 303 (1.20) | 58 (0.35) | 1.16 (0.97, 1.34) |
| Arthralgia | 142 (0.56) | 69 (0.42) | 0.22 (0.08, 0.36) |

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|---|---|---|---|
| Back pain | 68 (0.27) | 51 (0.31) | 0.00 (-0.11, 0.11) |
| Musculoskeletal stiffness | 22 (0.09) | 9 (0.05) | 0.06 (-0.00, 0.11) |
| Neck pain | 19 (0.08) | 22 (0.13) | -0.04 (-0.10, 0.03) |
| Muscle spasms | 15 (0.06) | 13 (0.08) | -0.02 (-0.07, 0.04) |
| Osteoarthritis | 12 (0.05) | 3 (0.02) | 0.03 (-0.01, 0.06) |
| Tendonitis | 9 (0.04) | 2 (0.01) | 0.02 (-0.01, 0.05) |
| Rotator cuff syndrome | 8 (0.03) | 3 (0.02) | 0.02 (-0.01, 0.05) |
| Limb discomfort | 7 (0.03) | 5 (0.03) | 0.01 (-0.02, 0.05) |

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|---|---|---|---|
| Joint swelling | 6 (0.02) | 5 (0.03) | -0.00 (-0.03, 0.03) |
| Musculoskeletal chest pain | 6 (0.02) | 8 (0.05) | -0.02 (-0.06, 0.02) |
| Musculoskeletal pain | 6 (0.02) | 1 (<0.01) | 0.02 (-0.01, 0.04) |
| Pain in jaw | 6 (0.02) | 0 (0.00) | 0.02 (0.00, 0.04) |
| Bursitis | 5 (0.02) | 7 (0.04) | -0.03 (-0.06, 0.01) |
| Arthritis | 4 (0.02) | 2 (0.01) | -0.00 (-0.02, 0.02) |
| Costochondritis | 4 (0.02) | 3 (0.02) | -0.00 (-0.03, 0.03) |
| Limb mass | 4 (0.02) | 2 (0.01) | 0.01 (-0.01, 0.04) |

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|---|---|---|---|
| Muscular weakness | 4 (0.02) | 2 (0.01) | -0.00 (-0.02, 0.02) |
| Bone pain | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.03) |
| Flank pain | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.03) |
| Groin pain | 3 (0.01) | 1 (<0.01) | 0.01 (-0.01, 0.03) |
| Intervertebral disc protrusion | 3 (0.01) | 3 (0.02) | -0.01 (-0.04, 0.02) |
| Joint stiffness | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.03) |
| Muscle swelling | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.03) |
| Axillary mass | 2 (<0.01) | 5 (0.03) | -0.02 (-0.04, 0.01) |

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|---|---|---|---|
| Muscle twitching | 2 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.02) |
| Musculoskeletal discomfort | 2 (<0.01) | 1 (<0.01) | 0.00 (-0.02, 0.02) |
| Trigger finger | 2 (<0.01) | 3 (0.02) | -0.01 (-0.04, 0.01) |
| Coccydynia | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Exostosis | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |
| Facet joint syndrome | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Fibromyalgia | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.01, 0.01) |
| Joint effusion | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

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MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

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| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Muscle contracture | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Muscle fatigue | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Muscle fibrosis | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Muscle mass | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Muscle rigidity | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Muscle tightness | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Neck mass | 1 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.01) |
| Nodal osteoarthritis | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Patellofemoral pain syndrome | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Plantar fasciitis | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |
| Polymyalgia rheumatica | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Psoriatic arthropathy | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Rhabdomyolysis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Soft tissue swelling | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Spinal osteoarthritis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Synovial cyst | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |

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|---|---|---|---|
| Synovitis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Temporomandibular joint syndrome | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Tenosynovitis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Tenosynovitis stenosans | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Arthritis reactive | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Chest wall mass | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Medial tibial stress syndrome | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Muscle discomfort | 0 (0.00) | 2 (0.01) | -0.01 (-0.02, 0.00) |

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|---|---|---|---|
| Myalgia intercostal | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Osteonecrosis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Osteopenia | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Rheumatoid arthritis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Spinal pain | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Torticollis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Infections and infestations | 666 (2.63), (2.44, 2.84) | 500 (3.04), (2.79, 3.32) | -0.28 (-0.61, 0.06) |
| Upper respiratory tract infection | 96 (0.38) | 51 (0.31) | 0.09 (-0.02, 0.21) |

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|---|---|---|---|
| Urinary tract infection | 58 (0.23) | 43 (0.26) | -0.03 (-0.12, 0.07) |
| COVID-19 | 43 (0.17) | 40 (0.24) | -0.12 (-0.21, -0.02) |
| Sinusitis | 33 (0.13) | 31 (0.19) | -0.06 (-0.14, 0.02) |
| Viral infection | 31 (0.12) | 17 (0.10) | -0.00 (-0.07, 0.07) |
| Gastroenteritis | 24 (0.09) | 24 (0.15) | -0.02 (-0.09, 0.05) |
| Nasopharyngitis | 21 (0.08) | 19 (0.12) | -0.00 (-0.06, 0.06) |
| Ear infection | 18 (0.07) | 11 (0.07) | 0.01 (-0.04, 0.06) |
| Tonsillitis | 18 (0.07) | 7 (0.04) | 0.04 (-0.00, 0.09) |

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|---|---|---|---|
| Rhinitis | 15 (0.06) | 10 (0.06) | 0.02 (-0.03, 0.07) |
| Cellulitis | 13 (0.05) | 8 (0.05) | -0.00 (-0.05, 0.04) |
| Suspected COVID-19 | 13 (0.05) | 11 (0.07) | -0.02 (-0.07, 0.03) |
| Tooth abscess | 13 (0.05) | 16 (0.10) | -0.03 (-0.09, 0.03) |
| Herpes zoster | 12 (0.05) | 11 (0.07) | -0.02 (-0.07, 0.03) |
| Oral herpes | 11 (0.04) | 15 (0.09) | -0.03 (-0.08, 0.03) |
| Tooth infection | 11 (0.04) | 24 (0.15) | -0.10 (-0.16, -0.03) |
| Diverticulitis | 10 (0.04) | 4 (0.02) | 0.01 (-0.02, 0.04) |

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|---|---|---|---|
| Influenza | 10 (0.04) | 2 (0.01) | 0.04 (0.00, 0.07) |
| Pharyngitis | 10 (0.04) | 4 (0.02) | 0.01 (-0.02, 0.05) |
| Pharyngitis streptococcal | 10 (0.04) | 5 (0.03) | -0.00 (-0.04, 0.04) |
| Viral upper respiratory tract infection | 10 (0.04) | 5 (0.03) | 0.01 (-0.03, 0.05) |
| Folliculitis | 9 (0.04) | 4 (0.02) | 0.02 (-0.02, 0.05) |
| Cystitis | 8 (0.03) | 1 (<0.01) | 0.03 (0.00, 0.06) |
| Lower respiratory tract infection | 8 (0.03) | 11 (0.07) | -0.02 (-0.06, 0.03) |
| Pneumonia | 7 (0.03) | 2 (0.01) | 0.01 (-0.02, 0.04) |

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|---|---|---|---|
| Bronchitis | 6 (0.02) | 2 (0.01) | 0.01 (-0.02, 0.03) |
| Furuncle | 6 (0.02) | 4 (0.02) | 0.01 (-0.02, 0.04) |
| Herpes simplex | 6 (0.02) | 0 (0.00) | 0.02 (0.00, 0.04) |
| Otitis media | 6 (0.02) | 6 (0.04) | -0.01 (-0.04, 0.02) |
| Abscess limb | 5 (0.02) | 4 (0.02) | -0.00 (-0.03, 0.03) |
| Acute sinusitis | 5 (0.02) | 5 (0.03) | -0.02 (-0.05, 0.02) |
| Appendicitis | 5 (0.02) | 5 (0.03) | -0.01 (-0.04, 0.02) |
| Conjunctivitis | 5 (0.02) | 9 (0.05) | -0.03 (-0.07, 0.01) |

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|---|---|---|---|
| Hordeolum | 5 (0.02) | 6 (0.04) | -0.02 (-0.05, 0.01) |
| Bacterial vaginosis | 4 (0.02) | 4 (0.02) | -0.01 (-0.03, 0.02) |
| COVID-19 pneumonia | 4 (0.02) | 5 (0.03) | -0.01 (-0.05, 0.02) |
| Eye infection | 4 (0.02) | 1 (<0.01) | 0.01 (-0.01, 0.03) |
| Gastroenteritis viral | 4 (0.02) | 3 (0.02) | -0.01 (-0.03, 0.02) |
| Genital herpes | 4 (0.02) | 1 (<0.01) | 0.01 (-0.01, 0.03) |
| Groin abscess | 4 (0.02) | 1 (<0.01) | 0.01 (-0.01, 0.03) |
| Skin infection | 4 (0.02) | 1 (<0.01) | 0.01 (-0.01, 0.03) |

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|---|---|---|---|
| Vulvovaginal candidiasis | 4 (0.02) | 3 (0.02) | 0.00 (-0.02, 0.03) |
| Vulvovaginal mycotic infection | 4 (0.02) | 0 (0.00) | 0.01 (0.00, 0.03) |
| Fungal infection | 3 (0.01) | 3 (0.02) | -0.01 (-0.04, 0.02) |
| Fungal skin infection | 3 (0.01) | 2 (0.01) | 0.00 (-0.02, 0.02) |
| Gingival abscess | 3 (0.01) | 3 (0.02) | -0.01 (-0.03, 0.02) |
| Helicobacter infection | 3 (0.01) | 2 (0.01) | 0.00 (-0.02, 0.02) |
| Laryngitis | 3 (0.01) | 1 (<0.01) | 0.01 (-0.01, 0.03) |
| Localised infection | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Oral candidiasis | 3 (0.01) | 5 (0.03) | -0.01 (-0.04, 0.02) |
| Otitis externa | 3 (0.01) | 3 (0.02) | -0.01 (-0.03, 0.02) |
| Sinusitis bacterial | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.03) |
| Subcutaneous abscess | 3 (0.01) | 1 (<0.01) | 0.01 (-0.01, 0.02) |
| Tinea pedis | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.03) |
| Viral pharyngitis | 3 (0.01) | 1 (<0.01) | 0.00 (-0.01, 0.02) |
| Abscess | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Candida infection | 2 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.02) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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|---|---|---|---|
| Chlamydial infection | 2 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.02) |
| Gastrointestinal infection | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Gonorrhoea | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Infected dermal cyst | 2 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.02) |
| Labyrinthitis | 2 (<0.01) | 3 (0.02) | -0.01 (-0.03, 0.02) |
| Osteomyelitis | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Post procedural infection | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Rash pustular | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Varicella zoster virus infection | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Abdominal abscess | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Appendicitis perforated | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.02) |
| Arthritis bacterial | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Atypical pneumonia | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Bacterial prostatitis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Bed bug infestation | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Body tinea | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |

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|---|---|---|---|
| Chromoblastomycosis | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Chronic sinusitis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Dysentery | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Ear infection bacterial | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Ear infection fungal | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Ear lobe infection | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.01, 0.01) |
| Empyema | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Epstein-Barr virus infection | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

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|---|---|---|---|
| Erysipelas | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Gastroenteritis bacterial | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Gonococcal infection | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| HIV infection | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Hepatitis B | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Herpes ophthalmic | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Herpes zoster reactivation | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Impetigo | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.01, 0.01) |

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MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

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| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Infected bite | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.01, 0.01) |
| Infected cyst | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Lice infestation | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Lyme disease | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Molluscum contagiosum | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.02) |
| Nasal vestibulitis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Oral fungal infection | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Oropharyngeal gonococcal infection | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Pericoronitis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Pharyngeal abscess | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Pharyngitis bacterial | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Pilonidal cyst | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |
| Postoperative wound infection | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Pulmonary tuberculosis | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Pulpitis dental | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |
| Respiratory tract infection | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

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|---|---|---|---|
| Respiratory tract infection viral | 1 (<0.01) | 2 (0.01) | -0.01 (-0.02, 0.01) |
| Sebaceous gland infection | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Septic shock | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |
| Staphylococcal infection | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Taeniasis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Tinea cruris | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Tinea versicolour | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.01, 0.01) |
| Urethritis | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Urinary tract infection bacterial | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Urosepsis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Vaginal infection | 1 (<0.01) | 2 (0.01) | -0.01 (-0.03, 0.01) |
| Vestibular neuronitis | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Viral diarrhoea | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Viral labyrinthitis | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Vulvitis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Abscess neck | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |

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|---|---|---|---|
| Abscess oral | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Acarodermatitis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Anal abscess | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Asymptomatic COVID-19 | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Balanitis candida | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Bartholinitis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Breast abscess | 0 (0.00) | 2 (0.01) | -0.01 (-0.03, 0.00) |
| Candida urethritis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |

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|---|---|---|---|
| Carbuncle | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Cat scratch disease | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Clostridium difficile infection | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Epididymitis | 0 (0.00) | 2 (0.01) | -0.01 (-0.02, 0.00) |
| Epiglottitis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Genital abscess | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Genitourinary chlamydia infection | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Gingivitis | 0 (0.00) | 4 (0.02) | -0.02 (-0.04, -0.00) |

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|---|---|---|---|
| Infectious mononucleosis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Infective exacerbation of chronic obstructive airways disease | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Kidney infection | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Lip infection | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Lung abscess | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Medical device site infection | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Mycoplasma infection | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Onychomycosis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |

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|---|---|---|---|
| Oral infection | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Otitis media acute | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Paronychia | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Pelvic inflammatory disease | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Perichondritis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Periorbital cellulitis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Pyelonephritis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Pyelonephritis acute | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |

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|---|---|---|---|
| Root canal infection | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Sepsis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Sexually transmitted disease | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Sialoadenitis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Syphilis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Tinea barbae | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Tonsillitis bacterial | 0 (0.00) | 3 (0.02) | -0.02 (-0.03, 0.00) |
| Viral sinusitis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |

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|---|---|---|---|
| Viral tonsillitis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Wound infection | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Gastrointestinal disorders | 508 (2.01), (1.84, 2.19) | 340 (2.07), (1.86, 2.30) | 0.16 (-0.12, 0.44) |
| Nausea | 156 (0.62) | 95 (0.58) | 0.12 (-0.03, 0.28) |
| Diarrhoea | 144 (0.57) | 123 (0.75) | -0.11 (-0.28, 0.05) |
| Vomiting | 53 (0.21) | 32 (0.19) | 0.03 (-0.06, 0.12) |
| Abdominal pain | 31 (0.12) | 13 (0.08) | 0.06 (-0.00, 0.13) |
| Abdominal pain upper | 26 (0.10) | 12 (0.07) | 0.03 (-0.03, 0.09) |

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|---|---|---|---|
| Gastrooesophageal reflux disease | 25 (0.10) | 16 (0.10) | 0.01 (-0.05, 0.07) |
| Dyspepsia | 18 (0.07) | 8 (0.05) | 0.04 (-0.01, 0.09) |
| Toothache | 17 (0.07) | 16 (0.10) | -0.02 (-0.08, 0.03) |
| Constipation | 12 (0.05) | 12 (0.07) | -0.03 (-0.08, 0.02) |
| Gastritis | 11 (0.04) | 2 (0.01) | 0.04 (0.00, 0.07) |
| Abdominal discomfort | 8 (0.03) | 3 (0.02) | 0.02 (-0.01, 0.05) |
| Food poisoning | 7 (0.03) | 3 (0.02) | 0.01 (-0.02, 0.04) |
| Dry mouth | 6 (0.02) | 1 (<0.01) | 0.02 (-0.00, 0.05) |

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|---|---|---|---|
| Irritable bowel syndrome | 6 (0.02) | 4 (0.02) | 0.00 (-0.03, 0.03) |
| Abdominal pain lower | 5 (0.02) | 4 (0.02) | -0.00 (-0.03, 0.03) |
| Dental caries | 5 (0.02) | 3 (0.02) | -0.00 (-0.02, 0.02) |
| Haemorrhoids | 4 (0.02) | 5 (0.03) | -0.01 (-0.05, 0.02) |
| Abdominal distension | 3 (0.01) | 2 (0.01) | 0.01 (-0.02, 0.03) |
| Anal fissure | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.03) |
| Faeces soft | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Flatulence | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.03) |

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|---|---|---|---|
| Gingival recession | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Large intestine polyp | 3 (0.01) | 1 (<0.01) | 0.00 (-0.01, 0.02) |
| Mouth ulceration | 3 (0.01) | 5 (0.03) | -0.01 (-0.04, 0.02) |
| Paraesthesia oral | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.03) |
| Rectal haemorrhage | 3 (0.01) | 1 (<0.01) | 0.01 (-0.01, 0.02) |
| Stomatitis | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Tooth impacted | 3 (0.01) | 2 (0.01) | -0.00 (-0.02, 0.02) |
| Colitis | 2 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.02) |

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|---|---|---|---|
| Gingival bleeding | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Gingival pain | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Inguinal hernia | 2 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.02) |
| Lip swelling | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Pancreatitis acute | 2 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.02) |
| Abdominal tenderness | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Aphthous ulcer | 1 (<0.01) | 2 (0.01) | -0.01 (-0.03, 0.01) |
| Ascites | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

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| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Cannabinoid hyperemesis syndrome | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Change of bowel habit | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Chronic gastritis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Colitis microscopic | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Crohn's disease | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Diarrhoea haemorrhagic | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Diverticulum | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.02) |
| Duodenogastric reflux | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

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|---|---|---|---|
| Dysphagia | 1 (<0.01) | 2 (0.01) | -0.01 (-0.03, 0.01) |
| Frequent bowel movements | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Gastrointestinal motility disorder | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Gastrointestinal polyp haemorrhage | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Glossitis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Haematemesis | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |
| Impaired gastric emptying | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |
| Intestinal obstruction | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

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|---|---|---|---|
| Lip blister | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Loose tooth | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Mouth cyst | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Odynophagia | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.01, 0.01) |
| Oesophageal dilatation | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Oral blood blister | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Oral disorder | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Pancreatitis | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |

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|---|---|---|---|
| Parotid gland enlargement | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.02) |
| Retching | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |
| Salivary duct obstruction | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Salivary gland enlargement | 1 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.01) |
| Swollen tongue | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Tooth loss | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Umbilical hernia | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Uvulitis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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|---|---|---|---|
| Vomiting projectile | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Abdominal mass | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Abdominal wall mass | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Diverticulum intestinal | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Duodenal ulcer | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Epigastric discomfort | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Gastric haemorrhage | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Gastritis erosive | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |

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|---|---|---|---|
| Gastrointestinal pain | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Gastrointestinal sounds abnormal | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Gingival discomfort | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Gingival swelling | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Haemorrhoidal haemorrhage | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Hiatus hernia | 0 (0.00) | 2 (0.01) | -0.01 (-0.03, 0.00) |
| Hyperaesthesia teeth | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Hypoaesthesia oral | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |

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|---|---|---|---|
| Noninfective gingivitis | 0 (0.00) | 2 (0.01) | -0.01 (-0.03, 0.00) |
| Periodontal disease | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Tongue blistering | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Tongue disorder | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Tongue eruption | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Tongue ulceration | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Respiratory, thoracic and mediastinal disorders | 494 (1.95), (1.79, 2.13) | 397 (2.42), (2.19, 2.66) | -0.18 (-0.48, 0.11) |
| Oropharyngeal pain | 135 (0.53) | 120 (0.73) | -0.05 (-0.20, 0.11) |

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|---|---|---|---|
| Nasal congestion | 127 (0.50) | 93 (0.57) | -0.08 (-0.23, 0.07) |
| Cough | 118 (0.47) | 109 (0.66) | -0.14 (-0.29, 0.01) |
| Rhinorrhoea | 91 (0.36) | 92 (0.56) | -0.11 (-0.24, 0.02) |
| Dyspnoea | 48 (0.19) | 29 (0.18) | 0.02 (-0.06, 0.11) |
| Asthma | 13 (0.05) | 12 (0.07) | -0.02 (-0.07, 0.04) |
| Sneezing | 13 (0.05) | 12 (0.07) | -0.01 (-0.05, 0.04) |
| Epistaxis | 11 (0.04) | 11 (0.07) | -0.01 (-0.06, 0.03) |
| Throat irritation | 11 (0.04) | 4 (0.02) | 0.02 (-0.01, 0.06) |

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|---|---|---|---|
| Rhinitis allergic | 10 (0.04) | 6 (0.04) | 0.00 (-0.04, 0.04) |
| Sinus congestion | 10 (0.04) | 3 (0.02) | 0.02 (-0.02, 0.05) |
| Wheezing | 10 (0.04) | 5 (0.03) | 0.01 (-0.02, 0.05) |
| Paranasal sinus discomfort | 6 (0.02) | 1 (<0.01) | 0.02 (-0.01, 0.04) |
| Dry throat | 5 (0.02) | 5 (0.03) | -0.00 (-0.03, 0.03) |
| Sinus pain | 5 (0.02) | 2 (0.01) | 0.01 (-0.01, 0.04) |
| Pharyngeal erythema | 4 (0.02) | 0 (0.00) | 0.01 (0.00, 0.03) |
| Dysphonia | 3 (0.01) | 1 (<0.01) | 0.01 (-0.01, 0.03) |

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|---|---|---|---|
| Pneumonia aspiration | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Productive cough | 3 (0.01) | 4 (0.02) | -0.01 (-0.04, 0.02) |
| Chronic obstructive pulmonary disease | 2 (<0.01) | 3 (0.02) | -0.01 (-0.03, 0.01) |
| Dyspnoea exertional | 2 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.02) |
| Nasal obstruction | 2 (<0.01) | 5 (0.03) | -0.02 (-0.04, 0.01) |
| Nasal turbinate hypertrophy | 2 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.02) |
| Pulmonary congestion | 2 (<0.01) | 2 (0.01) | -0.01 (-0.03, 0.01) |
| Pulmonary embolism | 2 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.02) |

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|---|---|---|---|
| Pulmonary mass | 2 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.02) |
| Respiratory disorder | 2 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.02) |
| Upper-airway cough syndrome | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Hiccups | 1 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.01) |
| Laryngeal polyp | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Nasal mucosal disorder | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Nasal mucosal ulcer | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Nasal polyps | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

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|---|---|---|---|
| Nasal septum deviation | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Oropharyngeal discomfort | 1 (<0.01) | 2 (0.01) | -0.01 (-0.03, 0.01) |
| Pharyngeal hypoaesthesia | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Pharyngeal inflammation | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Pharyngeal swelling | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Pleurisy | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Pneumonitis | 1 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.01) |
| Pulmonary pain | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Reflux laryngitis | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Respiratory tract congestion | 1 (<0.01) | 2 (0.01) | -0.01 (-0.02, 0.01) |
| Rhinalgia | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Sinus disorder | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Sputum discoloured | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Tachypnoea | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Throat tightness | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |
| Tonsillar inflammation | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Tonsillar ulcer | 1 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.01) |
| Hyperventilation | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Hypoxia | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Laryngeal disorder | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Laryngeal oedema | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Lung disorder | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Nasal discomfort | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Nasal disorder | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |

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|---|---|---|---|
| Pleuritic pain | 0 (0.00) | 3 (0.02) | -0.02 (-0.03, 0.00) |
| Respiratory symptom | 0 (0.00) | 2 (0.01) | -0.01 (-0.02, 0.00) |
| Sinonasal obstruction | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Tonsillar hypertrophy | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Skin and subcutaneous tissue disorders | 316 (1.25), (1.12, 1.39) | 165 (1.00), (0.86, 1.17) | 0.36 (0.15, 0.56) |
| Rash | 78 (0.31) | 40 (0.24) | 0.07 (-0.03, 0.18) |
| Pruritus | 46 (0.18) | 13 (0.08) | 0.13 (0.06, 0.20) |
| Urticaria | 24 (0.09) | 7 (0.04) | 0.05 (0.00, 0.10) |

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MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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|---|---|---|---|
| Erythema | 23 (0.09) | 6 (0.04) | 0.06 (0.01, 0.11) |
| Dermatitis contact | 17 (0.07) | 4 (0.02) | 0.04 (-0.00, 0.08) |
| Hyperhidrosis | 16 (0.06) | 3 (0.02) | 0.05 (0.01, 0.09) |
| Rash pruritic | 14 (0.06) | 4 (0.02) | 0.04 (0.00, 0.08) |
| Acne | 12 (0.05) | 6 (0.04) | 0.01 (-0.03, 0.05) |
| Cold sweat | 8 (0.03) | 2 (0.01) | 0.03 (-0.00, 0.06) |
| Dermatitis | 8 (0.03) | 8 (0.05) | -0.01 (-0.05, 0.03) |
| Night sweats | 7 (0.03) | 4 (0.02) | 0.01 (-0.02, 0.04) |

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|---|---|---|---|
| Ecchymosis | 6 (0.02) | 0 (0.00) | 0.02 (0.00, 0.04) |
| Rash papular | 6 (0.02) | 6 (0.04) | -0.00 (-0.04, 0.03) |
| Dermatitis atopic | 5 (0.02) | 2 (0.01) | 0.00 (-0.02, 0.03) |
| Rash maculo-papular | 5 (0.02) | 1 (<0.01) | 0.02 (-0.01, 0.04) |
| Eczema | 4 (0.02) | 12 (0.07) | -0.06 (-0.10, -0.01) |
| Miliaria | 4 (0.02) | 2 (0.01) | 0.01 (-0.01, 0.04) |
| Rash erythematous | 4 (0.02) | 7 (0.04) | -0.02 (-0.06, 0.01) |
| Skin lesion | 4 (0.02) | 3 (0.02) | -0.00 (-0.03, 0.03) |

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|---|---|---|---|
| Alopecia | 3 (0.01) | 2 (0.01) | -0.00 (-0.02, 0.02) |
| Dry skin | 3 (0.01) | 1 (<0.01) | 0.01 (-0.01, 0.03) |
| Ingrowing nail | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.03) |
| Blister | 2 (<0.01) | 2 (0.01) | -0.00 (-0.02, 0.02) |
| Dermal cyst | 2 (<0.01) | 3 (0.02) | -0.01 (-0.03, 0.01) |
| Dermatitis allergic | 2 (<0.01) | 3 (0.02) | -0.01 (-0.04, 0.01) |
| Pityriasis rosea | 2 (<0.01) | 2 (0.01) | -0.00 (-0.02, 0.02) |
| Psoriasis | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Rash macular | 2 (<0.01) | 2 (0.01) | -0.01 (-0.02, 0.01) |
| Sensitive skin | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Alopecia scarring | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Angioedema | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Capillaritis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Dermatitis acneiform | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Dermatosis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Diffuse alopecia | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

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|---|---|---|---|
| Drug eruption | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Eosinophilic cellulitis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Erythema nodosum | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Keratosis pilaris | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Lichenoid keratosis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Nail bed disorder | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Papule | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.01, 0.01) |
| Pemphigoid | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Prurigo | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Scab | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Scar pain | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.02) |
| Seborrhoeic dermatitis | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Skin burning sensation | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Skin discolouration | 1 (<0.01) | 2 (0.01) | -0.01 (-0.02, 0.01) |
| Skin disorder | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Skin hyperpigmentation | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

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|---|---|---|---|
| Skin hypopigmentation | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Skin striae | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Dermatitis psoriasiform | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Diabetic foot | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Hand dermatitis | 0 (0.00) | 2 (0.01) | -0.01 (-0.02, 0.00) |
| Hidradenitis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Keratolysis exfoliativa acquired | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Macule | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |

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|---|---|---|---|
| Onycholysis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Pain of skin | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Petechiae | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Pruritus allergic | 0 (0.00) | 3 (0.02) | -0.02 (-0.03, 0.00) |
| Purpura | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Rosacea | 0 (0.00) | 3 (0.02) | -0.02 (-0.04, 0.00) |
| Sebaceous gland disorder | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Skin exfoliation | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |

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|---|---|---|---|
| Skin mass | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Skin reaction | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Skin tightness | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Skin ulcer | 0 (0.00) | 4 (0.02) | -0.02 (-0.05, -0.00) |
| Injury, poisoning and procedural complications | 249 (0.98), (0.87, 1.11) | 158 (0.96), (0.82, 1.12) | 0.05 (-0.15, 0.25) |
| Contusion | 23 (0.09) | 9 (0.05) | 0.05 (-0.01, 0.10) |
| Skin laceration | 19 (0.08) | 11 (0.07) | 0.01 (-0.05, 0.06) |
| Muscle strain | 15 (0.06) | 7 (0.04) | 0.01 (-0.03, 0.05) |

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|---|---|---|---|
| Procedural pain | 15 (0.06) | 3 (0.02) | 0.03 (-0.00, 0.07) |
| Ligament sprain | 13 (0.05) | 14 (0.09) | -0.03 (-0.09, 0.02) |
| Fall | 11 (0.04) | 11 (0.07) | -0.02 (-0.06, 0.03) |
| Tooth fracture | 9 (0.04) | 9 (0.05) | -0.01 (-0.06, 0.03) |
| Animal bite | 8 (0.03) | 4 (0.02) | 0.00 (-0.03, 0.04) |
| Limb injury | 8 (0.03) | 4 (0.02) | 0.01 (-0.03, 0.04) |
| Ankle fracture | 7 (0.03) | 4 (0.02) | 0.00 (-0.03, 0.04) |
| Hand fracture | 6 (0.02) | 0 (0.00) | 0.02 (0.00, 0.04) |

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|---|---|---|---|
| Joint injury | 6 (0.02) | 4 (0.02) | -0.00 (-0.03, 0.03) |
| Rib fracture | 6 (0.02) | 2 (0.01) | 0.01 (-0.01, 0.04) |
| Road traffic accident | 5 (0.02) | 1 (<0.01) | 0.02 (-0.01, 0.04) |
| Skin abrasion | 5 (0.02) | 4 (0.02) | -0.01 (-0.04, 0.03) |
| Back injury | 4 (0.02) | 3 (0.02) | -0.00 (-0.03, 0.02) |
| Concussion | 4 (0.02) | 3 (0.02) | -0.01 (-0.03, 0.02) |
| Meniscus injury | 4 (0.02) | 2 (0.01) | -0.00 (-0.02, 0.02) |
| Thermal burn | 4 (0.02) | 5 (0.03) | -0.01 (-0.04, 0.02) |

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|---|---|---|---|
| Arthropod bite | 3 (0.01) | 3 (0.02) | -0.01 (-0.03, 0.02) |
| Foot fracture | 3 (0.01) | 3 (0.02) | -0.01 (-0.03, 0.02) |
| Joint dislocation | 3 (0.01) | 2 (0.01) | -0.00 (-0.02, 0.02) |
| Muscle injury | 3 (0.01) | 1 (<0.01) | 0.01 (-0.01, 0.02) |
| Soft tissue injury | 3 (0.01) | 4 (0.02) | -0.01 (-0.03, 0.02) |
| Vaccination complication | 3 (0.01) | 2 (0.01) | 0.01 (-0.02, 0.03) |
| Wound | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Alcohol poisoning | 2 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.02) |

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|---|---|---|---|
| Arthropod sting | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Cartilage injury | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Chillblains | 2 (<0.01) | 2 (0.01) | 0.00 (-0.02, 0.02) |
| Epicondylitis | 2 (<0.01) | 3 (0.02) | -0.01 (-0.03, 0.01) |
| Facial bones fracture | 2 (<0.01) | 2 (0.01) | -0.00 (-0.02, 0.02) |
| Forearm fracture | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Nerve injury | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Post procedural fever | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Post procedural hypotension | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Post vaccination syndrome | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Post-traumatic neck syndrome | 2 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.02) |
| Procedural dizziness | 2 (<0.01) | 2 (0.01) | -0.00 (-0.02, 0.02) |
| Procedural headache | 2 (<0.01) | 3 (0.02) | -0.01 (-0.03, 0.02) |
| Procedural nausea | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Procedural vomiting | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Radius fracture | 2 (<0.01) | 2 (0.01) | -0.01 (-0.03, 0.01) |

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|---|---|---|---|
| Sunburn | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Tibia fracture | 2 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.02) |
| Tongue injury | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Tooth injury | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Upper limb fracture | 2 (<0.01) | 2 (0.01) | -0.01 (-0.03, 0.01) |
| Wrist fracture | 2 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.02) |
| Accidental overdose | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Bone contusion | 1 (<0.01) | 2 (0.01) | -0.01 (-0.03, 0.01) |

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| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Burns second degree | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Clavicle fracture | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Conjunctival abrasion | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Corneal abrasion | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Electric shock | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Exposure to communicable disease | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Eyelid abrasion | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Femur fracture | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Fibula fracture | 1 (<0.01) | 3 (0.02) | -0.02 (-0.04, 0.01) |
| Frostbite | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Head injury | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.01, 0.01) |
| Heat stroke | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Human bite | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Iliotibial band syndrome | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |
| Incision site pain | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Intentional overdose | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Ligament rupture | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Lip injury | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Muscle contusion | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Musculoskeletal injury | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |
| Overdose | 1 (<0.01) | 2 (0.01) | -0.01 (-0.03, 0.01) |
| Post procedural discomfort | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Post procedural haematoma | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Post procedural pruritus | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

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|---|---|---|---|
| Post procedural swelling | 1 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.01) |
| Post-traumatic pain | 1 (<0.01) | 2 (0.01) | -0.01 (-0.02, 0.01) |
| Scratch | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Snake bite | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Splenic rupture | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Stab wound | 1 (<0.01) | 2 (0.01) | -0.01 (-0.02, 0.01) |
| Synovial rupture | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Tendon injury | 1 (<0.01) | 2 (0.01) | -0.01 (-0.02, 0.01) |

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|---|---|---|---|
| Tendon rupture | 1 (<0.01) | 2 (0.01) | -0.01 (-0.03, 0.01) |
| Traumatic fracture | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Traumatic haematoma | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Eye contusion | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Eye injury | 0 (0.00) | 3 (0.02) | -0.02 (-0.03, 0.00) |
| Femoral neck fracture | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Foreign body in ear | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Injury | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |

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|---|---|---|---|
| Ligament injury | 0 (0.00) | 2 (0.01) | -0.01 (-0.02, 0.00) |
| Limb fracture | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Lumbar vertebral fracture | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Mouth injury | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Muscle rupture | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Post procedural haemorrhage | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Procedural hypertension | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Scar | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |

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|---|---|---|---|
| Spinal column injury | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Toxicity to various agents | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Traumatic arthritis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Wound dehiscence | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Psychiatric disorders | 147 (0.58), (0.49, 0.68) | 80 (0.49), (0.39, 0.61) | 0.10 (-0.04, 0.25) |
| Anxiety | 44 (0.17) | 27 (0.16) | 0.01 (-0.07, 0.09) |
| Depression | 28 (0.11) | 16 (0.10) | 0.01 (-0.05, 0.08) |
| Insomnia | 24 (0.09) | 14 (0.09) | 0.02 (-0.04, 0.08) |

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|---|---|---|---|
| Attention deficit hyperactivity disorder | 10 (0.04) | 8 (0.05) | -0.02 (-0.06, 0.02) |
| Sleep disorder | 5 (0.02) | 1 (<0.01) | 0.02 (-0.01, 0.04) |
| Suicidal ideation | 4 (0.02) | 1 (<0.01) | 0.01 (-0.01, 0.03) |
| Abnormal dreams | 3 (0.01) | 1 (<0.01) | 0.01 (-0.01, 0.02) |
| Panic attack | 3 (0.01) | 1 (<0.01) | 0.00 (-0.01, 0.02) |
| Anxiety disorder | 2 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.02) |
| Depressed mood | 2 (<0.01) | 3 (0.02) | -0.01 (-0.03, 0.01) |
| Major depression | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Post-traumatic stress disorder | 2 (<0.01) | 1 (<0.01) | 0.01 (-0.01, 0.02) |
| Alcohol abuse | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Anger | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Bipolar II disorder | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Bipolar disorder | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |
| Borderline personality disorder | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.01, 0.01) |
| Confusional state | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Delirium tremens | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Dependence | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Depressive symptom | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.02) |
| Disorientation | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Drug abuse | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Generalised anxiety disorder | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.02) |
| Hallucination | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Homicidal ideation | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Hypervigilance | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

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|---|---|---|---|
| Intermittent explosive disorder | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Listless | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Mania | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |
| Menopausal depression | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Mixed anxiety and depressive disorder | 1 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.01) |
| Nightmare | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Obsessive-compulsive disorder | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Restlessness | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Schizophrenia | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Stress | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Substance abuse | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Agitation | 0 (0.00) | 2 (0.01) | -0.01 (-0.03, 0.00) |
| Alcoholism | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Hypomania | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Libido decreased | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Mental disorder | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |

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|---|---|---|---|
| Somnambulism | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Terminal insomnia | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Vascular disorders | 147 (0.58), (0.49, 0.68) | 87 (0.53), (0.42, 0.65) | 0.09 (-0.06, 0.24) |
| Hypertension | 102 (0.40) | 70 (0.43) | 0.00 (-0.13, 0.14) |
| Flushing | 7 (0.03) | 5 (0.03) | -0.00 (-0.03, 0.03) |
| Hot flush | 7 (0.03) | 3 (0.02) | 0.02 (-0.01, 0.04) |
| Hypotension | 7 (0.03) | 3 (0.02) | 0.01 (-0.02, 0.04) |
| Haematoma | 6 (0.02) | 1 (<0.01) | 0.02 (-0.01, 0.04) |

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|---|---|---|---|
| White coat hypertension | 3 (0.01) | 1 (<0.01) | 0.01 (-0.01, 0.02) |
| Deep vein thrombosis | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Hypertensive crisis | 2 (<0.01) | 1 (<0.01) | 0.00 (-0.02, 0.02) |
| Peripheral coldness | 2 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.02) |
| Varicose vein | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Achenbach syndrome | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Arteriosclerosis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Diastolic hypertension | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

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|---|---|---|---|
| Essential hypertension | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Pallor | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Peripheral arterial occlusive disease | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Raynaud's phenomenon | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Thrombophlebitis superficial | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Thrombosis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Phlebitis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Systolic hypertension | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |

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MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

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| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Blood and lymphatic system disorders | 140 (0.55), (0.47, 0.65) | 64 (0.39), (0.30, 0.50) | 0.23 (0.09, 0.36) |
| Lymphadenopathy | 107 (0.42) | 51 (0.31) | 0.18 (0.06, 0.30) |
| Lymph node pain | 10 (0.04) | 4 (0.02) | 0.02 (-0.02, 0.06) |
| Anaemia | 9 (0.04) | 3 (0.02) | 0.02 (-0.01, 0.05) |
| Iron deficiency anaemia | 6 (0.02) | 3 (0.02) | 0.00 (-0.02, 0.03) |
| Lymphadenitis | 3 (0.01) | 1 (<0.01) | 0.01 (-0.01, 0.02) |
| Anaemia vitamin B12 deficiency | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Blood loss anaemia | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

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|---|---|---|---|
| Increased tendency to bruise | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Normocytic anaemia | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Pancytopenia | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Leukocytosis | 0 (0.00) | 2 (0.01) | -0.01 (-0.03, 0.01) |
| Macrocytosis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Investigations | 122 (0.48), (0.40, 0.58) | 83 (0.51), (0.40, 0.63) | 0.07 (-0.07, 0.21) |
| Blood pressure increased | 31 (0.12) | 24 (0.15) | 0.01 (-0.06, 0.08) |
| Respiratory rate increased | 15 (0.06) | 20 (0.12) | -0.03 (-0.09, 0.03) |

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|---|---|---|---|
| Body temperature increased | 14 (0.06) | 3 (0.02) | 0.04 (0.01, 0.08) |
| SARS-CoV-2 test positive | 10 (0.04) | 10 (0.06) | -0.03 (-0.08, 0.01) |
| Heart rate increased | 8 (0.03) | 0 (0.00) | 0.03 (0.01, 0.05) |
| Blood pressure diastolic increased | 7 (0.03) | 5 (0.03) | 0.01 (-0.03, 0.04) |
| Cardiac murmur | 6 (0.02) | 2 (0.01) | 0.01 (-0.01, 0.04) |
| Blood pressure systolic increased | 4 (0.02) | 2 (0.01) | 0.01 (-0.02, 0.03) |
| Prostatic specific antigen increased | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.03) |
| Blood cholesterol increased | 2 (<0.01) | 3 (0.02) | -0.01 (-0.04, 0.02) |

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|---|---|---|---|
| Blood glucose increased | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Haemoglobin decreased | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Liver function test increased | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Weight decreased | 2 (<0.01) | 3 (0.02) | -0.01 (-0.03, 0.01) |
| Alanine aminotransferase increased | 1 (<0.01) | 2 (0.01) | -0.01 (-0.02, 0.01) |
| Blood phosphorus decreased | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Blood testosterone decreased | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Blood triglycerides increased | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

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|---|---|---|---|
| Body temperature abnormal | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Body temperature normal | 1 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.01) |
| Capillary nail refill test abnormal | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Cardiac murmur functional | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Colonoscopy | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Endoscopy upper gastrointestinal tract | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Heart rate decreased | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Heart rate irregular | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Heart sounds abnormal | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Heparin-induced thrombocytopenia test | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Lipids increased | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Mammogram abnormal | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Oxygen saturation decreased | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Smear cervix abnormal | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Blood creatinine increased | 0 (0.00) | 2 (0.01) | -0.01 (-0.03, 0.00) |
| Blood potassium decreased | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |

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|---|---|---|---|
| Blood pressure difference of extremities | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Blood uric acid increased | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Colposcopy abnormal | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Electrocardiogram QT prolonged | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Glomerular filtration rate decreased | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Lymph node palpable | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Occult blood positive | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| SARS-CoV-2 test | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |

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|---|---|---|---|
| Weight increased | 0 (0.00) | 3 (0.02) | -0.02 (-0.04, 0.00) |
| Metabolism and nutrition disorders | 86 (0.34), (0.27, 0.42) | 65 (0.40), (0.31, 0.50) | -0.07 (-0.19, 0.05) |
| Decreased appetite | 23 (0.09) | 14 (0.09) | 0.03 (-0.03, 0.09) |
| Type 2 diabetes mellitus | 18 (0.07) | 9 (0.05) | 0.00 (-0.05, 0.05) |
| Gout | 9 (0.04) | 7 (0.04) | -0.01 (-0.05, 0.03) |
| Hypercholesterolaemia | 6 (0.02) | 5 (0.03) | -0.01 (-0.04, 0.02) |
| Hypoglycaemia | 5 (0.02) | 2 (0.01) | 0.01 (-0.02, 0.03) |
| Hyperlipidaemia | 4 (0.02) | 2 (0.01) | -0.00 (-0.02, 0.02) |

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|---|---|---|---|
| Vitamin D deficiency | 4 (0.02) | 5 (0.03) | -0.02 (-0.05, 0.01) |
| Dehydration | 3 (0.01) | 3 (0.02) | -0.01 (-0.03, 0.02) |
| Iron deficiency | 3 (0.01) | 1 (<0.01) | 0.01 (-0.01, 0.02) |
| Vitamin B12 deficiency | 3 (0.01) | 2 (0.01) | -0.00 (-0.03, 0.02) |
| Dyslipidaemia | 2 (<0.01) | 1 (<0.01) | 0.00 (-0.02, 0.02) |
| Obesity | 2 (<0.01) | 2 (0.01) | -0.01 (-0.03, 0.01) |
| Diabetic ketoacidosis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Electrolyte imbalance | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

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|---|---|---|---|
| Hypoferritinaemia | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Hypokalaemia | 1 (<0.01) | 4 (0.02) | -0.02 (-0.05, 0.00) |
| Hyponatraemia | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |
| Insulin resistance | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Polydipsia | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Diabetes mellitus | 0 (0.00) | 5 (0.03) | -0.03 (-0.06, -0.00) |
| Glucose tolerance impaired | 0 (0.00) | 2 (0.01) | -0.01 (-0.03, 0.01) |
| Hyperglycaemia | 0 (0.00) | 3 (0.02) | -0.02 (-0.04, 0.00) |

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|---|---|---|---|
| Hypovitaminosis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Lactic acidosis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Eye disorders | 77 (0.30), (0.24, 0.38) | 46 (0.28), (0.21, 0.37) | 0.07 (-0.04, 0.17) |
| Conjunctival haemorrhage | 8 (0.03) | 0 (0.00) | 0.04 (0.01, 0.06) |
| Photophobia | 8 (0.03) | 0 (0.00) | 0.04 (0.01, 0.06) |
| Dry eye | 6 (0.02) | 5 (0.03) | -0.00 (-0.03, 0.03) |
| Lacrimation increased | 6 (0.02) | 3 (0.02) | 0.01 (-0.02, 0.04) |
| Eye pruritus | 5 (0.02) | 3 (0.02) | 0.01 (-0.02, 0.04) |

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|---|---|---|---|
| Swelling of eyelid | 4 (0.02) | 0 (0.00) | 0.01 (0.00, 0.03) |
| Cataract | 3 (0.01) | 2 (0.01) | -0.00 (-0.02, 0.02) |
| Conjunctivitis allergic | 3 (0.01) | 4 (0.02) | -0.01 (-0.03, 0.02) |
| Eye swelling | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.03) |
| Ocular discomfort | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Ocular hyperaemia | 3 (0.01) | 2 (0.01) | -0.00 (-0.02, 0.02) |
| Visual impairment | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.03) |
| Diplopia | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Eye pain | 2 (<0.01) | 5 (0.03) | -0.02 (-0.05, 0.01) |
| Glaucoma | 2 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.02) |
| Retinal haemorrhage | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Uveitis | 2 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.02) |
| Vision blurred | 2 (<0.01) | 2 (0.01) | -0.00 (-0.02, 0.02) |
| Vitreous detachment | 2 (<0.01) | 2 (0.01) | -0.00 (-0.02, 0.02) |
| Vitreous floaters | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Chalazion | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

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|---|---|---|---|
| Episcleritis | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Eye discharge | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Eye inflammation | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Eye irritation | 1 (<0.01) | 2 (0.01) | -0.01 (-0.03, 0.01) |
| Iridocyclitis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Iritis | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |
| Keratitis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Macular oedema | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

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| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Miosis | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Ocular hypertension | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Periorbital swelling | 1 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.01) |
| Posterior capsule opacification | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Ulcerative keratitis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Blepharitis | 0 (0.00) | 3 (0.02) | -0.02 (-0.03, 0.00) |
| Corneal oedema | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Dacryostenosis acquired | 0 (0.00) | 2 (0.01) | -0.01 (-0.02, 0.00) |

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|---|---|---|---|
| Eyelid oedema | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Eyelid ptosis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Optic disc disorder | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Periorbital pain | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Pseudo-blepharoptosis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Retinal degeneration | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Retinal tear | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Reproductive system and breast disorders | 73 (0.29), (0.23, 0.36) | 39 (0.24), (0.17, 0.32) | 0.06 (-0.04, 0.16) |

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|---|---|---|---|
| Dysmenorrhoea | 15 (0.06) | 6 (0.04) | 0.02 (-0.02, 0.06) |
| Menstruation irregular | 6 (0.02) | 1 (<0.01) | 0.02 (-0.00, 0.04) |
| Benign prostatic hyperplasia | 5 (0.02) | 1 (<0.01) | 0.01 (-0.01, 0.03) |
| Breast mass | 4 (0.02) | 2 (0.01) | 0.00 (-0.02, 0.02) |
| Dysfunctional uterine bleeding | 3 (0.01) | 2 (0.01) | 0.01 (-0.02, 0.03) |
| Menorrhagia | 3 (0.01) | 2 (0.01) | 0.00 (-0.02, 0.02) |
| Menstrual disorder | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.03) |
| Ovarian cyst | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Breast tenderness | 2 (<0.01) | 1 (<0.01) | 0.00 (-0.02, 0.02) |
| Cervical polyp | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Erectile dysfunction | 2 (<0.01) | 2 (0.01) | -0.00 (-0.02, 0.02) |
| Pelvic pain | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Postmenopausal haemorrhage | 2 (<0.01) | 3 (0.02) | -0.01 (-0.03, 0.02) |
| Vaginal discharge | 2 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.02) |
| Balanoposthitis | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Bartholin's cyst | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Breast calcifications | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Breast cyst | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |
| Endometrial hyperplasia | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Genital paraesthesia | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Genital rash | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Haematospermia | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Menometrorrhagia | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Metrorrhagia | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.01, 0.01) |

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|---|---|---|---|
| Nipple pain | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Orchitis noninfective | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Penile discharge | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Pruritus genital | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Scrotal pain | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Scrotal swelling | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Testicular cyst | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Testis discomfort | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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|---|---|---|---|
| Uterine polyp | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Vaginal haemorrhage | 1 (<0.01) | 3 (0.02) | -0.02 (-0.04, 0.01) |
| Vulval disorder | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Vulvovaginal dryness | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Breast pain | 0 (0.00) | 2 (0.01) | -0.01 (-0.02, 0.00) |
| Endometriosis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Menopausal symptoms | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Polycystic ovaries | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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|---|---|---|---|
| Premenstrual syndrome | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Prostatitis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Testicular mass | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Testicular pain | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Testicular swelling | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Uterine cyst | 0 (0.00) | 2 (0.01) | -0.01 (-0.03, 0.00) |
| Uterine pain | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Ear and labyrinth disorders | 65 (0.26), (0.20, 0.33) | 34 (0.21), (0.14, 0.29) | 0.07 (-0.02, 0.16) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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|---|---|---|---|
| Vertigo | 18 (0.07) | 8 (0.05) | 0.02 (-0.02, 0.07) |
| Tinnitus | 12 (0.05) | 7 (0.04) | 0.01 (-0.04, 0.05) |
| Ear pain | 11 (0.04) | 10 (0.06) | -0.01 (-0.05, 0.04) |
| Cerumen impaction | 5 (0.02) | 2 (0.01) | 0.01 (-0.02, 0.03) |
| Ear discomfort | 5 (0.02) | 3 (0.02) | 0.01 (-0.02, 0.03) |
| Ear canal erythema | 2 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.02) |
| Ear congestion | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Eustachian tube dysfunction | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Deafness | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |
| Ear deformity acquired | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Ear swelling | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Excessive cerumen production | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Hypoacusis | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Meniere's disease | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Middle ear effusion | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Paraesthesia ear | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

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|---|---|---|---|
| Tympanic membrane perforation | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.01, 0.01) |
| Otorrhoea | 0 (0.00) | 2 (0.01) | -0.01 (-0.02, 0.00) |
| Cardiac disorders | 49 (0.19), (0.14, 0.26) | 27 (0.16), (0.11, 0.24) | 0.04 (-0.05, 0.12) |
| Palpitations | 14 (0.06) | 4 (0.02) | 0.04 (0.00, 0.08) |
| Tachycardia | 9 (0.04) | 9 (0.05) | -0.02 (-0.06, 0.02) |
| Atrial fibrillation | 7 (0.03) | 2 (0.01) | 0.01 (-0.01, 0.04) |
| Angina pectoris | 2 (<0.01) | 2 (0.01) | -0.00 (-0.02, 0.02) |
| Arrhythmia | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

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|---|---|---|---|
| Bradycardia | 2 (<0.01) | 1 (<0.01) | 0.00 (-0.02, 0.02) |
| Cardiac arrest | 2 (<0.01) | 3 (0.02) | -0.01 (-0.04, 0.01) |
| Cardiac failure congestive | 2 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.02) |
| Acute coronary syndrome | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Acute left ventricular failure | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Acute myocardial infarction | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |
| Atrioventricular block complete | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Atrioventricular block first degree | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

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|---|---|---|---|
| Cardiac failure | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Congestive cardiomyopathy | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Extrasystoles | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Myocardial infarction | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Myocarditis | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Sinus tachycardia | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Stress cardiomyopathy | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Supraventricular extrasystoles | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

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|---|---|---|---|
| Supraventricular tachycardia | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Ventricular extrasystoles | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Aortic valve incompetence | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Atrial flutter | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Coronary artery disease | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Sinus bradycardia | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Immune system disorders | 38 (0.15), (0.11, 0.21) | 11 (0.07), (0.03, 0.12) | 0.08 (0.02, 0.15) |
| Seasonal allergy | 15 (0.06) | 5 (0.03) | 0.02 (-0.02, 0.06) |

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|---|---|---|---|
| Hypersensitivity | 7 (0.03) | 1 (<0.01) | 0.02 (-0.00, 0.05) |
| Allergy to vaccine | 6 (0.02) | 0 (0.00) | 0.03 (0.01, 0.05) |
| Drug hypersensitivity | 4 (0.02) | 1 (<0.01) | 0.01 (-0.01, 0.03) |
| Food allergy | 3 (0.01) | 1 (<0.01) | 0.01 (-0.01, 0.02) |
| Allergic reaction to excipient | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Allergy to arthropod bite | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Allergy to chemicals | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Allergy to metals | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

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**Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Allergy to animal | 0 (0.00) | 2 (0.01) | -0.01 (-0.02, 0.00) |
| Dust allergy | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Renal and urinary disorders | 24 (0.09), (0.06, 0.14) | 15 (0.09), (0.05, 0.15) | 0.00 (-0.06, 0.06) |
| Dysuria | 6 (0.02) | 1 (<0.01) | 0.02 (-0.00, 0.04) |
| Nephrolithiasis | 6 (0.02) | 4 (0.02) | -0.01 (-0.04, 0.02) |
| Haematuria | 4 (0.02) | 0 (0.00) | 0.02 (0.00, 0.03) |
| Incontinence | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Acute kidney injury | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t13_1_1.rtf. Generated from t_unsol_sum_subsas 18JUL2021 20:16

**Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Chromaturia | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Cystitis noninfective | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Pollakiuria | 1 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.01) |
| Urethral discharge | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Urinary incontinence | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Vesicoureteric reflux | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Chronic kidney disease | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Costovertebral angle tenderness | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

File Name: t13_1_1.rtf. Generated from t_unsol_sum_sub.sas 18JUL2021 20:16

**Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Hypertonic bladder | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Micturition urgency | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Neurogenic bladder | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Nocturia | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Proteinuria | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Renal pain | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Urethral dilatation | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Urinary retention | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

File Name: t13_1_1.rtf. Generated from t_unsol_sum_sub.sas 18JUL2021 20:16

**Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 23 (0.09), (0.06, 0.14) | 10 (0.06), (0.03, 0.11) | 0.03 (-0.02, 0.09) |
| Breast cancer | 4 (0.02) | 0 (0.00) | 0.02 (0.00, 0.03) |
| Melanocytic naevus | 4 (0.02) | 2 (0.01) | 0.00 (-0.02, 0.03) |
| Lipoma | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.03) |
| Malignant melanoma | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Uterine leiomyoma | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Basal cell carcinoma | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Benign breast neoplasm | 1 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.01) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t13_1_1.rtf. Generated from t_unsol_sum_subsas 18JUL2021 20:16

**Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Borderline serous tumour of ovary | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Craniopharyngioma | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Prostate cancer | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Pyogenic granuloma | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Skin papilloma | 1 (<0.01) | 1 (<0.01) | 0.00 (-0.01, 0.01) |
| Testis cancer | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Anogenital warts | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Fibroadenoma of breast | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

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**Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Neoplasm skin | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Penile wart | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Rectal adenocarcinoma | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Soft tissue neoplasm | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Uncoded | 14 (0.06), (0.03, 0.09) | 5 (0.03), (0.01, 0.07) | 0.03 (-0.01, 0.08) |
| Uncoded | 8 (0.03) | 4 (0.02) | 0.02 (-0.01, 0.06) |
| BLOOD CLOTS IN PERIOD | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| CHOLECYSTITIS AND CHOLELITHIASIS | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| LEFT ARM PAIN/SORENESS | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| LEFT LOWER MOLAR TOOTH REMOVAL SECONDARY TO INFECTION | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| RT LOWER TOOTH IMPLANT | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| SUBMANDIBULAR SWELLING BILATERAL | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| TOOTH EXTRACTION (14TH MOLAR) | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| UPPER LEFT SECOND MOLAR ECTRACTION | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Endocrine disorders | 12 (0.05), (0.02, 0.08) | 5 (0.03), (0.01, 0.07) | 0.01 (-0.03, 0.05) |
| Hypothyroidism | 6 (0.02) | 3 (0.02) | 0.00 (-0.03, 0.03) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

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**Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Thyroid mass | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.03) |
| Adrenal mass | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Autoimmune thyroiditis | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.02, 0.01) |
| Basedow's disease | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Hyperthyroidism | 1 (<0.01) | 1 (<0.01) | -0.00 (-0.01, 0.01) |
| Hepatobiliary disorders | 11 (0.04), (0.02, 0.08) | 6 (0.04), (0.01, 0.08) | 0.01 (-0.03, 0.05) |
| Cholelithiasis | 4 (0.02) | 2 (0.01) | 0.01 (-0.02, 0.03) |
| Cholecystitis acute | 3 (0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t13_1_1.rtf. Generated from t_unsol_sum_subsas 18JUL2021 20:16

**Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Cholecystitis | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Cirrhosis alcoholic | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Nonalcoholic fatty liver disease | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Gallbladder disorder | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Hepatic steatosis | 0 (0.00) | 3 (0.02) | -0.02 (-0.04, 0.00) |
| Pregnancy, puerperium and perinatal conditions | 5 (0.02), (0.01, 0.05) | 2 (0.01), (0.00, 0.04) | 0.01 (-0.02, 0.03) |
| Abortion spontaneous | 3 (0.01) | 1 (<0.01) | 0.01 (-0.01, 0.03) |
| Pregnancy | 2 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t13_1_1.rtf. Generated from t_unsol_sum_subsas 18JUL2021 20:16

**Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Hyperemesis gravidarum | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Surgical and medical procedures | 2 (<0.01), (0.00, 0.03) | 4 (0.02), (0.01, 0.06) | -0.02 (-0.05, 0.01) |
| Immunisation | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Knee arthroplasty | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Cataract operation | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Implantable defibrillator replacement | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Knee operation | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Wisdom teeth removal | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t13_1_1.rtf. Generated from t_unsol_sum_subsas 18JUL2021 20:16

**Table 13.1.1 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Congenital, familial and genetic disorders | 0 (0.00), (0.00, 0.01) | 1 (<0.01), (0.00, 0.03) | -0.01 (-0.02, 0.01) |
| Neurofibromatosis | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.01) |
| Social circumstances | 0 (0.00), (0.00, 0.01) | 5 (0.03), (0.01, 0.07) | -0.03 (-0.05, -0.00) |
| Menopause | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Partner stress | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |
| Physical assault | 0 (0.00) | 2 (0.01) | -0.01 (-0.02, 0.00) |
| Stress at work | 0 (0.00) | 1 (<0.01) | -0.01 (-0.02, 0.00) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t13_1_1.rtf. Generated from t_unsol_sum_sub.sas 18JUL2021 20:16

**Table 13.1.2 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Any unsolicited AEs | 1083 (22.68), (21.49, 23.89) | 639 (18.47), (17.19, 19.81) | 7.20 (5.44, 8.97) |
| General disorders and administration site conditions | 407 (8.52), (7.74, 9.35) | 120 (3.47), (2.88, 4.13) | 6.61 (5.55, 7.67) |
| Injection site pain | 145 (3.04) | 21 (0.61) | 2.97 (2.35, 3.60) |
| Fatigue | 115 (2.41) | 46 (1.33) | 1.54 (0.93, 2.15) |
| Pyrexia | 34 (0.71) | 2 (0.06) | 0.75 (0.46, 1.04) |
| Injection site pruritus | 28 (0.59) | 1 (0.03) | 0.65 (0.39, 0.90) |
| Injection site erythema | 25 (0.52) | 2 (0.06) | 0.58 (0.32, 0.84) |
| Chills | 22 (0.46) | 2 (0.06) | 0.49 (0.25, 0.72) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

File Name: t13_1_2.rtf. Generated from t_unsol_sum_sub.sas 18JUL2021 20:16

**Table 13.1.2 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Pain | 22 (0.46) | 5 (0.14) | 0.38 (0.13, 0.63) |
| Injection site swelling | 21 (0.44) | 3 (0.09) | 0.43 (0.20, 0.67) |
| Malaise | 19 (0.40) | 8 (0.23) | 0.23 (-0.03, 0.49) |
| Influenza like illness | 15 (0.31) | 4 (0.12) | 0.26 (0.04, 0.48) |
| Injection site bruising | 9 (0.19) | 1 (0.03) | 0.20 (0.04, 0.35) |
| Vaccination site pain | 9 (0.19) | 5 (0.14) | 0.09 (-0.10, 0.29) |
| Feeling hot | 6 (0.13) | 0 (0.00) | 0.15 (0.03, 0.28) |
| Oedema peripheral | 6 (0.13) | 3 (0.09) | 0.01 (-0.13, 0.14) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

File Name: t13_1_2.rtf. Generated from t_unsol_sum_sub.sas 18JUL2021 20:16

**Table 13.1.2 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Injection site discomfort | 5 (0.10) | 2 (0.06) | 0.07 (-0.07, 0.21) |
| Asthenia | 4 (0.08) | 0 (0.00) | 0.08 (0.00, 0.15) |
| Chest discomfort | 4 (0.08) | 2 (0.06) | 0.04 (-0.07, 0.16) |
| Injection site inflammation | 4 (0.08) | 0 (0.00) | 0.10 (0.00, 0.20) |
| Peripheral swelling | 4 (0.08) | 1 (0.03) | 0.06 (-0.06, 0.17) |
| Tenderness | 4 (0.08) | 0 (0.00) | 0.10 (0.00, 0.20) |
| Feeling cold | 3 (0.06) | 0 (0.00) | 0.08 (-0.01, 0.16) |
| Inflammation | 3 (0.06) | 3 (0.09) | -0.00 (-0.12, 0.12) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

File Name: t13_1_2.rtf. Generated from t_unsol_sum_sub.sas 18JUL2021 20:16

**Table 13.1.2 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Vaccination site bruising | 3 (0.06) | 1 (0.03) | 0.05 (-0.05, 0.15) |
| Injection site mass | 2 (0.04) | 1 (0.03) | 0.03 (-0.06, 0.11) |
| Injection site paraesthesia | 2 (0.04) | 0 (0.00) | 0.05 (-0.02, 0.12) |
| Injection site rash | 2 (0.04) | 1 (0.03) | 0.03 (-0.06, 0.11) |
| Injection site reaction | 2 (0.04) | 1 (0.03) | 0.02 (-0.06, 0.10) |
| Injection site warmth | 2 (0.04) | 0 (0.00) | 0.04 (-0.02, 0.10) |
| Non-cardiac chest pain | 2 (0.04) | 2 (0.06) | -0.00 (-0.10, 0.10) |
| Vaccination site swelling | 2 (0.04) | 1 (0.03) | 0.03 (-0.06, 0.11) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

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|---|---|---|---|
| Axillary pain | 1 (0.02) | 1 (0.03) | -0.01 (-0.07, 0.05) |
| Chest pain | 1 (0.02) | 1 (0.03) | -0.01 (-0.09, 0.08) |
| Discomfort | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Feeling abnormal | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Hangover | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Injection site coldness | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Injection site dermatitis | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Injection site haematoma | 1 (0.02) | 1 (0.03) | -0.01 (-0.07, 0.05) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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|---|---|---|---|
| Injection site haemorrhage | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Injection site hypoaesthesia | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Injection site joint pain | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Injection site scab | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Injection site scar | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Nodule | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Swelling | 1 (0.02) | 2 (0.06) | -0.03 (-0.11, 0.06) |
| Swelling face | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Vaccination site discomfort | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Vaccination site induration | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Vaccination site pruritus | 1 (0.02) | 1 (0.03) | -0.00 (-0.07, 0.07) |
| Crepitations | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Hyperpyrexia | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Impaired healing | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Induration | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Suprapubic pain | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Thirst | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Vaccination site erythema | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Vaccination site joint pain | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Vaccination site paraesthesia | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Vessel puncture site bruise | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Vessel puncture site swelling | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Musculoskeletal and connective tissue disorders | 286 (5.99), (5.33, 6.70) | 98 (2.83), (2.31, 3.44) | 4.18 (3.25, 5.11) |
| Pain in extremity | 107 (2.24) | 14 (0.40) | 2.34 (1.80, 2.88) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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|---|---|---|---|
| Myalgia | 94 (1.97) | 22 (0.64) | 1.68 (1.15, 2.20) |
| Arthralgia | 30 (0.63) | 29 (0.84) | -0.07 (-0.45, 0.31) |
| Back pain | 16 (0.34) | 16 (0.46) | -0.08 (-0.36, 0.21) |
| Musculoskeletal stiffness | 6 (0.13) | 0 (0.00) | 0.15 (0.03, 0.28) |
| Limb discomfort | 5 (0.10) | 0 (0.00) | 0.13 (0.02, 0.24) |
| Neck pain | 4 (0.08) | 4 (0.12) | -0.01 (-0.15, 0.13) |
| Osteoarthritis | 4 (0.08) | 3 (0.09) | -0.03 (-0.16, 0.11) |
| Tendonitis | 4 (0.08) | 1 (0.03) | 0.05 (-0.04, 0.14) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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|---|---|---|---|
| Joint stiffness | 3 (0.06) | 0 (0.00) | 0.08 (-0.01, 0.16) |
| Limb mass | 3 (0.06) | 0 (0.00) | 0.08 (-0.01, 0.16) |
| Rotator cuff syndrome | 3 (0.06) | 1 (0.03) | 0.03 (-0.05, 0.12) |
| Joint swelling | 2 (0.04) | 0 (0.00) | 0.04 (-0.02, 0.10) |
| Muscle spasms | 2 (0.04) | 2 (0.06) | -0.02 (-0.10, 0.07) |
| Muscle tightness | 2 (0.04) | 1 (0.03) | 0.03 (-0.06, 0.11) |
| Muscular weakness | 2 (0.04) | 1 (0.03) | 0.03 (-0.06, 0.11) |
| Arthritis | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |

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|---|---|---|---|
| Axillary mass | 1 (0.02) | 1 (0.03) | -0.00 (-0.07, 0.07) |
| Bone pain | 1 (0.02) | 1 (0.03) | -0.00 (-0.07, 0.07) |
| Bursitis | 1 (0.02) | 2 (0.06) | -0.05 (-0.15, 0.05) |
| Costochondritis | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Flank pain | 1 (0.02) | 1 (0.03) | -0.01 (-0.07, 0.05) |
| Groin pain | 1 (0.02) | 1 (0.03) | -0.00 (-0.07, 0.07) |
| Intervertebral disc protrusion | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Jaw cyst | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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|---|---|---|---|
| Metatarsalgia | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Musculoskeletal chest pain | 1 (0.02) | 1 (0.03) | -0.01 (-0.07, 0.05) |
| Musculoskeletal discomfort | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Musculoskeletal pain | 1 (0.02) | 2 (0.06) | -0.03 (-0.11, 0.06) |
| Myopathy | 1 (0.02) | 1 (0.03) | -0.00 (-0.07, 0.07) |
| Osteoporosis | 1 (0.02) | 1 (0.03) | -0.02 (-0.09, 0.06) |
| Pain in jaw | 1 (0.02) | 1 (0.03) | -0.01 (-0.09, 0.08) |
| Rheumatoid arthritis | 1 (0.02) | 1 (0.03) | -0.00 (-0.07, 0.07) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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|---|---|---|---|
| Spondylolisthesis | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Synovial cyst | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Torticollis | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Trigger finger | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Enthesopathy | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Fibromyalgia | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Foot deformity | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Muscle fatigue | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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|---|---|---|---|
| Periarthritis | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Plantar fasciitis | 0 (0.00) | 2 (0.06) | -0.06 (-0.14, 0.02) |
| Polyarthritis | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Spinal osteoarthritis | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Nervous system disorders | 219 (4.59), (4.01, 5.22) | 126 (3.64), (3.04, 4.32) | 1.76 (0.87, 2.65) |
| Headache | 142 (2.97) | 81 (2.34) | 1.29 (0.55, 2.02) |
| Lethargy | 20 (0.42) | 5 (0.14) | 0.37 (0.12, 0.61) |
| Dizziness | 19 (0.40) | 14 (0.40) | 0.02 (-0.25, 0.30) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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|---|---|---|---|
| Tension headache | 6 (0.13) | 2 (0.06) | 0.05 (-0.08, 0.19) |
| Dysgeusia | 4 (0.08) | 1 (0.03) | 0.07 (-0.04, 0.17) |
| Syncope | 4 (0.08) | 1 (0.03) | 0.06 (-0.04, 0.16) |
| Migraine | 3 (0.06) | 5 (0.14) | -0.06 (-0.21, 0.09) |
| Parosmia | 3 (0.06) | 2 (0.06) | 0.03 (-0.09, 0.14) |
| Taste disorder | 3 (0.06) | 0 (0.00) | 0.08 (-0.01, 0.16) |
| Paraesthesia | 2 (0.04) | 11 (0.32) | -0.23 (-0.41, -0.05) |
| Poor quality sleep | 2 (0.04) | 1 (0.03) | 0.03 (-0.06, 0.11) |

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|---|---|---|---|
| Presyncope | 2 (0.04) | 0 (0.00) | 0.04 (-0.02, 0.10) |
| Sciatica | 2 (0.04) | 3 (0.09) | -0.03 (-0.14, 0.09) |
| Somnolence | 2 (0.04) | 0 (0.00) | 0.04 (-0.02, 0.10) |
| Tremor | 2 (0.04) | 0 (0.00) | 0.04 (-0.02, 0.10) |
| Acoustic neuritis | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Ageusia | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Anosmia | 1 (0.02) | 1 (0.03) | -0.01 (-0.07, 0.05) |
| Burning sensation | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |

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|---|---|---|---|
| Carotid artery disease | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Carpal tunnel syndrome | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Cerebrovascular accident | 1 (0.02) | 1 (0.03) | -0.02 (-0.09, 0.06) |
| Cluster headache | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Hypersomnia | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Hypoaesthesia | 1 (0.02) | 2 (0.06) | -0.03 (-0.11, 0.04) |
| Lumbar radiculopathy | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Memory impairment | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |

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|---|---|---|---|
| Migraine with aura | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Neuralgia | 1 (0.02) | 1 (0.03) | -0.01 (-0.07, 0.05) |
| Sinus headache | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Balance disorder | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Disturbance in attention | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Head discomfort | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Loss of consciousness | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Nerve compression | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t13_1_2.rtf. Generated from t_unsol_sum_sub.sas 18JUL2021 20:16

**Table 13.1.2 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Neuropathy peripheral | 0 (0.00) | 2 (0.06) | -0.07 (-0.16, 0.03) |
| Post-traumatic headache | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Restless legs syndrome | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Infections and infestations | 143 (2.99), (2.53, 3.52) | 116 (3.35), (2.78, 4.01) | -0.16 (-0.94, 0.62) |
| Urinary tract infection | 25 (0.52) | 20 (0.58) | -0.00 (-0.33, 0.33) |
| Upper respiratory tract infection | 15 (0.31) | 11 (0.32) | -0.01 (-0.26, 0.24) |
| Sinusitis | 10 (0.21) | 3 (0.09) | 0.12 (-0.04, 0.28) |
| COVID-19 | 9 (0.19) | 4 (0.12) | 0.04 (-0.13, 0.21) |

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|---|---|---|---|
| Cellulitis | 6 (0.13) | 3 (0.09) | 0.03 (-0.12, 0.17) |
| Rhinitis | 6 (0.13) | 4 (0.12) | 0.04 (-0.12, 0.21) |
| Tooth abscess | 6 (0.13) | 5 (0.14) | 0.00 (-0.15, 0.15) |
| Viral infection | 6 (0.13) | 1 (0.03) | 0.09 (-0.03, 0.20) |
| Nasopharyngitis | 5 (0.10) | 10 (0.29) | -0.13 (-0.32, 0.07) |
| Tooth infection | 5 (0.10) | 7 (0.20) | -0.07 (-0.25, 0.12) |
| Oral herpes | 4 (0.08) | 6 (0.17) | -0.08 (-0.24, 0.09) |
| Conjunctivitis | 3 (0.06) | 0 (0.00) | 0.06 (-0.01, 0.13) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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|---|---|---|---|
| Cystitis | 3 (0.06) | 0 (0.00) | 0.07 (-0.01, 0.15) |
| Gingivitis | 3 (0.06) | 1 (0.03) | 0.05 (-0.05, 0.15) |
| Lower respiratory tract infection | 3 (0.06) | 2 (0.06) | 0.03 (-0.09, 0.14) |
| Helicobacter infection | 2 (0.04) | 0 (0.00) | 0.04 (-0.02, 0.10) |
| Otitis externa | 2 (0.04) | 0 (0.00) | 0.04 (-0.02, 0.10) |
| Viral upper respiratory tract infection | 2 (0.04) | 0 (0.00) | 0.03 (-0.01, 0.08) |
| Abscess rupture | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Appendicitis | 1 (0.02) | 1 (0.03) | -0.01 (-0.07, 0.05) |

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|---|---|---|---|
| Bronchitis | 1 (0.02) | 2 (0.06) | -0.04 (-0.13, 0.05) |
| Chronic sinusitis | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Diverticulitis | 1 (0.02) | 3 (0.09) | -0.07 (-0.17, 0.03) |
| Ear infection | 1 (0.02) | 4 (0.12) | -0.10 (-0.22, 0.02) |
| Folliculitis | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Fungal skin infection | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Gastroenteritis | 1 (0.02) | 2 (0.06) | -0.03 (-0.11, 0.04) |
| Gastroenteritis viral | 1 (0.02) | 1 (0.03) | -0.01 (-0.09, 0.08) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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|---|---|---|---|
| Hordeolum | 1 (0.02) | 1 (0.03) | -0.01 (-0.07, 0.05) |
| Infected cyst | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Intestinal gangrene | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Kidney infection | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Laryngitis | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Localised infection | 1 (0.02) | 2 (0.06) | -0.03 (-0.13, 0.06) |
| Onychomycosis | 1 (0.02) | 1 (0.03) | -0.01 (-0.09, 0.08) |
| Oral candidiasis | 1 (0.02) | 1 (0.03) | -0.00 (-0.07, 0.07) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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|---|---|---|---|
| Paronychia | 1 (0.02) | 1 (0.03) | -0.01 (-0.09, 0.08) |
| Pharyngitis | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Pneumonia | 1 (0.02) | 4 (0.12) | -0.09 (-0.21, 0.02) |
| Pneumonia bacterial | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Pulpitis dental | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Pustule | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Sepsis | 1 (0.02) | 1 (0.03) | -0.02 (-0.09, 0.06) |
| Skin infection | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |

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|---|---|---|---|
| Tinea pedis | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Tonsillitis | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Viral rhinitis | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Vulvovaginal candidiasis | 1 (0.02) | 1 (0.03) | -0.00 (-0.07, 0.07) |
| Vulvovaginal mycotic infection | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Wound infection | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Arthritis bacterial | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Bacterial infection | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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|---|---|---|---|
| COVID-19 pneumonia | 0 (0.00) | 3 (0.09) | -0.09 (-0.20, 0.01) |
| Herpes zoster | 0 (0.00) | 5 (0.14) | -0.13 (-0.24, -0.02) |
| Influenza | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Labyrinthitis | 0 (0.00) | 2 (0.06) | -0.05 (-0.12, 0.02) |
| Lower respiratory tract infection viral | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Otitis media | 0 (0.00) | 2 (0.06) | -0.06 (-0.14, 0.02) |
| Perichondritis | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Poliomyelitis | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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|---|---|---|---|
| Respiratory, thoracic and mediastinal disorders | 110 (2.30), (1.90, 2.77) | 65 (1.88), (1.45, 2.39) | 0.71 (0.07, 1.35) |
| Oropharyngeal pain | 29 (0.61) | 18 (0.52) | 0.22 (-0.11, 0.55) |
| Rhinorrhoea | 27 (0.57) | 18 (0.52) | 0.13 (-0.20, 0.45) |
| Cough | 22 (0.46) | 11 (0.32) | 0.18 (-0.09, 0.45) |
| Nasal congestion | 16 (0.34) | 16 (0.46) | -0.14 (-0.41, 0.14) |
| Epistaxis | 12 (0.25) | 2 (0.06) | 0.24 (0.06, 0.42) |
| Dyspnoea | 8 (0.17) | 10 (0.29) | -0.09 (-0.31, 0.14) |
| Productive cough | 3 (0.06) | 1 (0.03) | 0.05 (-0.05, 0.15) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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|---|---|---|---|
| Acute respiratory failure | 2 (0.04) | 0 (0.00) | 0.03 (-0.01, 0.08) |
| Asthma | 2 (0.04) | 4 (0.12) | -0.07 (-0.19, 0.06) |
| Dry throat | 2 (0.04) | 0 (0.00) | 0.05 (-0.02, 0.12) |
| Dysphonia | 2 (0.04) | 2 (0.06) | -0.01 (-0.12, 0.10) |
| Pulmonary embolism | 2 (0.04) | 1 (0.03) | -0.00 (-0.08, 0.08) |
| Rhinitis allergic | 2 (0.04) | 1 (0.03) | 0.02 (-0.06, 0.10) |
| Bronchospasm | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Chronic obstructive pulmonary disease | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |

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|---|---|---|---|
| Pharyngeal erythema | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Rales | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Sinus disorder | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Sleep apnoea syndrome | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Sneezing | 1 (0.02) | 2 (0.06) | -0.03 (-0.13, 0.06) |
| Throat irritation | 1 (0.02) | 1 (0.03) | -0.00 (-0.07, 0.07) |
| Allergic cough | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Nasal obstruction | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |

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|---|---|---|---|
| Paranasal sinus discomfort | 0 (0.00) | 2 (0.06) | -0.07 (-0.16, 0.03) |
| Respiratory tract congestion | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Wheezing | 0 (0.00) | 2 (0.06) | -0.06 (-0.14, 0.02) |
| Gastrointestinal disorders | 108 (2.26), (1.86, 2.72) | 81 (2.34), (1.86, 2.90) | 0.23 (-0.44, 0.89) |
| Diarrhoea | 34 (0.71) | 19 (0.55) | 0.25 (-0.10, 0.59) |
| Nausea | 24 (0.50) | 23 (0.66) | -0.08 (-0.43, 0.27) |
| Toothache | 8 (0.17) | 7 (0.20) | -0.00 (-0.19, 0.19) |
| Constipation | 6 (0.13) | 5 (0.14) | 0.02 (-0.15, 0.18) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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|---|---|---|---|
| Gastrooesophageal reflux disease | 6 (0.13) | 4 (0.12) | 0.02 (-0.15, 0.18) |
| Vomiting | 6 (0.13) | 5 (0.14) | 0.01 (-0.16, 0.18) |
| Abdominal distension | 4 (0.08) | 0 (0.00) | 0.08 (0.00, 0.15) |
| Abdominal discomfort | 3 (0.06) | 4 (0.12) | -0.04 (-0.18, 0.09) |
| Abdominal pain upper | 3 (0.06) | 0 (0.00) | 0.07 (-0.01, 0.15) |
| Dry mouth | 3 (0.06) | 1 (0.03) | 0.05 (-0.05, 0.15) |
| Abdominal pain | 2 (0.04) | 8 (0.23) | -0.16 (-0.32, -0.01) |
| Dyspepsia | 2 (0.04) | 3 (0.09) | -0.03 (-0.14, 0.09) |

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|---|---|---|---|
| Irritable bowel syndrome | 2 (0.04) | 1 (0.03) | 0.02 (-0.06, 0.10) |
| Mouth ulceration | 2 (0.04) | 0 (0.00) | 0.05 (-0.02, 0.12) |
| Abdominal pain lower | 1 (0.02) | 2 (0.06) | -0.03 (-0.13, 0.06) |
| Change of bowel habit | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Colitis microscopic | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Dental caries | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Dysphagia | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Flatulence | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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|---|---|---|---|
| Gastritis | 1 (0.02) | 1 (0.03) | -0.00 (-0.07, 0.07) |
| Gastrointestinal haemorrhage | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Gingival pain | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Haematochezia | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Inguinal hernia | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Large intestine polyp | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Malpositioned teeth | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Mesenteric artery thrombosis | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 13.1.2 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Oral pain | 1 (0.02) | 1 (0.03) | -0.01 (-0.07, 0.05) |
| Rectal haemorrhage | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Salivary gland enlargement | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Tongue discolouration | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Tooth malformation | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Anal incontinence | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Diverticulum | 0 (0.00) | 2 (0.06) | -0.05 (-0.12, 0.02) |
| Food poisoning | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Haemorrhoidal haemorrhage | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Hiatus hernia | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Lip ulceration | 0 (0.00) | 2 (0.06) | -0.06 (-0.14, 0.02) |
| Loose tooth | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Obstructive pancreatitis | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Oesophageal pain | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Small intestinal obstruction | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Tooth disorder | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Injury, poisoning and procedural complications | 65 (1.36), (1.05, 1.73) | 43 (1.24), (0.90, 1.67) | 0.16 (-0.35, 0.67) |
| Fall | 10 (0.21) | 9 (0.26) | -0.04 (-0.25, 0.18) |
| Contusion | 5 (0.10) | 4 (0.12) | -0.01 (-0.15, 0.14) |
| Procedural pain | 5 (0.10) | 1 (0.03) | 0.07 (-0.05, 0.18) |
| Ligament sprain | 3 (0.06) | 5 (0.14) | -0.10 (-0.26, 0.06) |
| Tooth fracture | 3 (0.06) | 0 (0.00) | 0.05 (-0.01, 0.11) |
| Ankle fracture | 2 (0.04) | 1 (0.03) | 0.01 (-0.06, 0.08) |
| Chest injury | 2 (0.04) | 0 (0.00) | 0.05 (-0.02, 0.12) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Dental restoration failure | 2 (0.04) | 0 (0.00) | 0.03 (-0.01, 0.08) |
| Injection related reaction | 2 (0.04) | 0 (0.00) | 0.05 (-0.02, 0.12) |
| Muscle strain | 2 (0.04) | 5 (0.14) | -0.09 (-0.24, 0.05) |
| Radius fracture | 2 (0.04) | 1 (0.03) | 0.02 (-0.06, 0.10) |
| Rib fracture | 2 (0.04) | 0 (0.00) | 0.04 (-0.02, 0.10) |
| Thermal burn | 2 (0.04) | 2 (0.06) | -0.01 (-0.10, 0.09) |
| Tibia fracture | 2 (0.04) | 0 (0.00) | 0.05 (-0.02, 0.12) |
| Ulna fracture | 2 (0.04) | 0 (0.00) | 0.05 (-0.02, 0.12) |

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| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Accidental overdose | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Arthropod bite | 1 (0.02) | 1 (0.03) | -0.02 (-0.09, 0.06) |
| Chillblains | 1 (0.02) | 1 (0.03) | -0.01 (-0.09, 0.08) |
| Face injury | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Femur fracture | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Hand fracture | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Head injury | 1 (0.02) | 2 (0.06) | -0.03 (-0.13, 0.06) |
| Joint dislocation | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Joint injury | 1 (0.02) | 2 (0.06) | -0.03 (-0.11, 0.06) |
| Ligament rupture | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Lip injury | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Muscle contusion | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Muscle injury | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Musculoskeletal injury | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Poisoning deliberate | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Post procedural erythema | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Post procedural fever | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Post procedural inflammation | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Post procedural pruritus | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Post procedural swelling | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Procedural nausea | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Road traffic accident | 1 (0.02) | 1 (0.03) | -0.00 (-0.07, 0.07) |
| Skin abrasion | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Skin laceration | 1 (0.02) | 4 (0.12) | -0.09 (-0.21, 0.04) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Stress fracture | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Traumatic fracture | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Upper limb fracture | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Urethral stricture postoperative | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Vaccination complication | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Wrist fracture | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Animal bite | 0 (0.00) | 2 (0.06) | -0.06 (-0.14, 0.02) |
| Arthropod sting | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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|---|---|---|---|
| Concussion | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Limb injury | 0 (0.00) | 4 (0.12) | -0.11 (-0.22, -0.00) |
| Sternal fracture | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Skin and subcutaneous tissue disorders | 63 (1.32), (1.02, 1.68) | 29 (0.84), (0.56, 1.20) | 0.66 (0.21, 1.12) |
| Pruritus | 11 (0.23) | 8 (0.23) | 0.06 (-0.15, 0.27) |
| Rash | 11 (0.23) | 5 (0.14) | 0.09 (-0.09, 0.28) |
| Erythema | 6 (0.13) | 1 (0.03) | 0.11 (-0.01, 0.23) |
| Dermatitis | 4 (0.08) | 0 (0.00) | 0.08 (0.00, 0.15) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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|---|---|---|---|
| Hyperhidrosis | 4 (0.08) | 0 (0.00) | 0.10 (0.00, 0.20) |
| Night sweats | 4 (0.08) | 1 (0.03) | 0.08 (-0.04, 0.19) |
| Dermal cyst | 3 (0.06) | 0 (0.00) | 0.07 (-0.01, 0.15) |
| Rash erythematous | 3 (0.06) | 1 (0.03) | 0.05 (-0.05, 0.15) |
| Rash pruritic | 2 (0.04) | 4 (0.12) | -0.05 (-0.17, 0.07) |
| Skin lesion | 2 (0.04) | 3 (0.09) | -0.05 (-0.16, 0.06) |
| Urticaria | 2 (0.04) | 3 (0.09) | -0.03 (-0.16, 0.09) |
| Acne | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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|---|---|---|---|
| Blister | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Dermatitis contact | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Dermatitis psoriasiform | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Ecchymosis | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Eczema | 1 (0.02) | 2 (0.06) | -0.03 (-0.11, 0.06) |
| Hair growth abnormal | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Rash macular | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Rash maculo-papular | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |

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|---|---|---|---|
| Rosacea | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Skin ulcer | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Stasis dermatitis | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Xeroderma | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Rhinophyma | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Skin irritation | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Skin reaction | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Vascular disorders | 59 (1.24), (0.94, 1.59) | 26 (0.75), (0.49, 1.10) | 0.56 (0.12, 1.00) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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|---|---|---|---|
| Hypertension | 46 (0.96) | 22 (0.64) | 0.43 (0.04, 0.83) |
| Haematoma | 2 (0.04) | 1 (0.03) | 0.01 (-0.08, 0.10) |
| Orthostatic hypotension | 2 (0.04) | 1 (0.03) | 0.01 (-0.08, 0.10) |
| Peripheral coldness | 2 (0.04) | 0 (0.00) | 0.04 (-0.02, 0.10) |
| Aortic stenosis | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Arteriosclerosis | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Blood pressure fluctuation | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Deep vein thrombosis | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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|---|---|---|---|
| Essential hypertension | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Flushing | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Systolic hypertension | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Thrombophlebitis superficial | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Thrombosis | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Intermittent claudication | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Pallor | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Investigations | 32 (0.67), (0.46, 0.94) | 19 (0.55), (0.33, 0.86) | 0.16 (-0.18, 0.50) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Blood pressure increased | 10 (0.21) | 7 (0.20) | 0.03 (-0.17, 0.24) |
| Cardiac murmur | 4 (0.08) | 1 (0.03) | 0.05 (-0.04, 0.14) |
| Body temperature increased | 2 (0.04) | 0 (0.00) | 0.05 (-0.02, 0.12) |
| Heart rate increased | 2 (0.04) | 0 (0.00) | 0.04 (-0.02, 0.10) |
| SARS-CoV-2 test positive | 2 (0.04) | 2 (0.06) | -0.03 (-0.14, 0.07) |
| Biopsy lymph gland | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Blood cholesterol increased | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Blood iron increased | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 13.1.2 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Blood pressure systolic increased | 1 (0.02) | 1 (0.03) | -0.01 (-0.07, 0.05) |
| Blood thyroid stimulating hormone increased | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Body temperature abnormal | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Computerised tomogram thorax abnormal | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Heart rate irregular | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Lymph node palpable | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Prostatic specific antigen increased | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Weight decreased | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Weight increased | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Angiogram | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Antibody test positive | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Aortic bruit | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Blood creatinine increased | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Blood pressure systolic | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Blood urea nitrogen/creatinine ratio increased | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Light chain analysis increased | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Tumour marker increased | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Metabolism and nutrition disorders | 26 (0.54), (0.36, 0.80) | 8 (0.23), (0.10, 0.46) | 0.29 (0.02, 0.56) |
| Hypercholesterolaemia | 6 (0.13) | 2 (0.06) | 0.07 (-0.05, 0.19) |
| Hypoglycaemia | 4 (0.08) | 0 (0.00) | 0.08 (0.00, 0.15) |
| Dehydration | 3 (0.06) | 0 (0.00) | 0.06 (-0.01, 0.13) |
| Dyslipidaemia | 2 (0.04) | 0 (0.00) | 0.04 (-0.02, 0.10) |
| Hyponatraemia | 2 (0.04) | 0 (0.00) | 0.04 (-0.02, 0.10) |
| Decreased appetite | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Diabetes mellitus inadequate control | 1 (0.02) | 1 (0.03) | -0.00 (-0.07, 0.07) |
| Folate deficiency | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Gout | 1 (0.02) | 1 (0.03) | -0.01 (-0.09, 0.07) |
| Hyperglycaemia | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Hyperkalaemia | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Hyperlipidaemia | 1 (0.02) | 2 (0.06) | -0.05 (-0.15, 0.05) |
| Hypocholesterolaemia | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Hypomagnesaemia | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Iron deficiency | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Type 2 diabetes mellitus | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Fluid retention | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Hypoalbuminaemia | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Hypophosphataemia | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Cardiac disorders | 22 (0.46), (0.29, 0.70) | 22 (0.64), (0.40, 0.96) | -0.16 (-0.49, 0.18) |
| Atrial fibrillation | 5 (0.10) | 4 (0.12) | -0.01 (-0.16, 0.15) |
| Bradycardia | 4 (0.08) | 2 (0.06) | 0.03 (-0.09, 0.14) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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|---|---|---|---|
| Palpitations | 3 (0.06) | 3 (0.09) | -0.00 (-0.12, 0.12) |
| Acute left ventricular failure | 2 (0.04) | 0 (0.00) | 0.03 (-0.01, 0.08) |
| Extrasystoles | 2 (0.04) | 1 (0.03) | 0.03 (-0.06, 0.11) |
| Angina pectoris | 1 (0.02) | 1 (0.03) | -0.00 (-0.07, 0.07) |
| Cardiac arrest | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Myocardial infarction | 1 (0.02) | 1 (0.03) | -0.02 (-0.09, 0.06) |
| Myocarditis | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Sinus bradycardia | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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|---|---|---|---|
| Tachycardia | 1 (0.02) | 2 (0.06) | -0.03 (-0.13, 0.06) |
| Acute myocardial infarction | 0 (0.00) | 2 (0.06) | -0.07 (-0.16, 0.03) |
| Arrhythmia | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Atrioventricular block complete | 0 (0.00) | 2 (0.06) | -0.05 (-0.12, 0.02) |
| Atrioventricular block first degree | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Bundle branch block right | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Myocardial ischaemia | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Ventricular extrasystoles | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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|---|---|---|---|
| Ear and labyrinth disorders | 20 (0.42), (0.26, 0.65) | 14 (0.40), (0.22, 0.68) | 0.08 (-0.21, 0.36) |
| Vertigo | 5 (0.10) | 5 (0.14) | -0.02 (-0.17, 0.13) |
| Ear pain | 4 (0.08) | 2 (0.06) | 0.04 (-0.09, 0.17) |
| Tinnitus | 3 (0.06) | 3 (0.09) | -0.03 (-0.16, 0.11) |
| Cerumen impaction | 2 (0.04) | 0 (0.00) | 0.03 (-0.01, 0.08) |
| Vertigo positional | 2 (0.04) | 0 (0.00) | 0.04 (-0.02, 0.10) |
| Ear congestion | 1 (0.02) | 1 (0.03) | -0.00 (-0.07, 0.07) |
| Ear discomfort | 1 (0.02) | 2 (0.06) | -0.03 (-0.11, 0.06) |

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|---|---|---|---|
| Eustachian tube dysfunction | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Excessive cerumen production | 1 (0.02) | 1 (0.03) | -0.00 (-0.07, 0.07) |
| Blood and lymphatic system disorders | 17 (0.36), (0.21, 0.57) | 12 (0.35), (0.18, 0.61) | 0.09 (-0.17, 0.36) |
| Lymphadenopathy | 15 (0.31) | 10 (0.29) | 0.10 (-0.15, 0.35) |
| Anaemia | 2 (0.04) | 1 (0.03) | 0.02 (-0.06, 0.10) |
| Increased tendency to bruise | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Splenic infarction | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Eye disorders | 16 (0.34), (0.19, 0.54) | 13 (0.38), (0.20, 0.64) | 0.01 (-0.25, 0.27) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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|---|---|---|---|
| Cataract | 2 (0.04) | 2 (0.06) | -0.01 (-0.10, 0.08) |
| Eye pruritus | 2 (0.04) | 0 (0.00) | 0.05 (-0.02, 0.12) |
| Lacrimation increased | 2 (0.04) | 3 (0.09) | -0.04 (-0.14, 0.06) |
| Photopsia | 2 (0.04) | 0 (0.00) | 0.05 (-0.02, 0.12) |
| Retinal tear | 2 (0.04) | 0 (0.00) | 0.03 (-0.01, 0.08) |
| Conjunctival haemorrhage | 1 (0.02) | 1 (0.03) | -0.00 (-0.07, 0.07) |
| Diplopia | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Dry eye | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

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|---|---|---|---|
| Halo vision | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Iritis | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Ocular hyperaemia | 1 (0.02) | 2 (0.06) | -0.04 (-0.13, 0.05) |
| Vision blurred | 1 (0.02) | 1 (0.03) | -0.00 (-0.07, 0.07) |
| Vitreous floaters | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Eye discharge | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Eye irritation | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Eye pain | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |

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| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Eye ulcer | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Glaucoma | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Periorbital swelling | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Renal and urinary disorders | 16 (0.34), (0.19, 0.54) | 9 (0.26), (0.12, 0.49) | 0.08 (-0.15, 0.31) |
| Acute kidney injury | 5 (0.10) | 3 (0.09) | 0.01 (-0.12, 0.14) |
| Urinary retention | 3 (0.06) | 0 (0.00) | 0.07 (-0.01, 0.15) |
| Haematuria | 2 (0.04) | 2 (0.06) | -0.01 (-0.10, 0.08) |
| Chronic kidney disease | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |

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|---|---|---|---|
| Dysuria | 1 (0.02) | 2 (0.06) | -0.03 (-0.11, 0.06) |
| Nocturia | 1 (0.02) | 1 (0.03) | -0.00 (-0.07, 0.07) |
| Pollakiuria | 1 (0.02) | 1 (0.03) | -0.02 (-0.09, 0.06) |
| Polyuria | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Proteinuria | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Urinary incontinence | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Urinary tract obstruction | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Psychiatric disorders | 12 (0.25), (0.13, 0.44) | 13 (0.38), (0.20, 0.64) | -0.08 (-0.32, 0.16) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
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|---|---|---|---|
| Depression | 3 (0.06) | 2 (0.06) | 0.01 (-0.09, 0.11) |
| Insomnia | 3 (0.06) | 6 (0.17) | -0.09 (-0.23, 0.06) |
| Anxiety | 1 (0.02) | 3 (0.09) | -0.06 (-0.17, 0.05) |
| Apathy | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Grief reaction | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Mental status changes | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Nightmare | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Restlessness | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t13_1_2.rtf. Generated from t_unsol_sum_sub.sas 18JUL2021 20:16

**Table 13.1.2 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Depressed mood | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Disorientation | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Immunisation anxiety related reaction | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 11 (0.23), (0.12, 0.41) | 13 (0.38), (0.20, 0.64) | -0.15 (-0.39, 0.09) |
| Prostate cancer | 3 (0.06) | 0 (0.00) | 0.05 (-0.01, 0.11) |
| Basal cell carcinoma | 2 (0.04) | 2 (0.06) | -0.02 (-0.12, 0.09) |
| Squamous cell carcinoma | 2 (0.04) | 1 (0.03) | -0.00 (-0.08, 0.08) |
| Breast cancer metastatic | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

File Name: t13_1_2.rtf. Generated from t_unsol_sum_sub.sas 18JUL2021 20:16

**Table 13.1.2 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Non-Hodgkin's lymphoma | 1 (0.02) | 1 (0.03) | -0.02 (-0.09, 0.06) |
| Penile cancer | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Prostate cancer recurrent | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Acrochordon | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Adenocarcinoma of appendix | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Benign oesophageal neoplasm | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Glioblastoma | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Lipoma | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t13_1_2.rtf. Generated from t_unsol_sum_sub.sas 18JUL2021 20:16

**Table 13.1.2 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Ovarian cancer | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Renal cell carcinoma | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Seborrhoeic keratosis | 0 (0.00) | 2 (0.06) | -0.05 (-0.12, 0.02) |
| Squamous cell carcinoma of the tongue | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Immune system disorders | 8 (0.17), (0.07, 0.33) | 2 (0.06), (0.01, 0.21) | 0.13 (-0.02, 0.27) |
| Allergy to vaccine | 2 (0.04) | 0 (0.00) | 0.05 (-0.02, 0.12) |
| Seasonal allergy | 2 (0.04) | 0 (0.00) | 0.04 (-0.02, 0.10) |
| Allergy to metals | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 13.1.2 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Food allergy | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Hypersensitivity | 1 (0.02) | 1 (0.03) | -0.01 (-0.07, 0.05) |
| Multiple allergies | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Allergy to arthropod bite | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Reproductive system and breast disorders | 7 (0.15), (0.06, 0.30) | 5 (0.14), (0.05, 0.34) | 0.00 (-0.18, 0.18) |
| Erectile dysfunction | 2 (0.04) | 0 (0.00) | 0.04 (-0.02, 0.10) |
| Breast cyst | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Prostatic mass | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t13_1_2.rtf. Generated from t_unsol_sum_subsas 18JUL2021 20:16

**Table 13.1.2 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Scrotal swelling | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Testicular pain | 1 (0.02) | 2 (0.06) | -0.04 (-0.13, 0.05) |
| Vaginal prolapse | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Benign prostatic hyperplasia | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Prostatomegaly | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Testicular cyst | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Uncoded | 4 (0.08), (0.02, 0.21) | 3 (0.09), (0.02, 0.25) | 0.03 (-0.11, 0.16) |
| Uncoded | 4 (0.08) | 3 (0.09) | 0.03 (-0.11, 0.16) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t13_1_2.rtf. Generated from t_unsol_sum_subsas 18JUL2021 20:16

**Table 13.1.2 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Endocrine disorders | 1 (0.02), (0.00, 0.12) | 1 (0.03), (0.00, 0.16) | -0.01 (-0.07, 0.05) |
| Basedow's disease | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Adrenal mass | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Hepatobiliary disorders | 1 (0.02), (0.00, 0.12) | 1 (0.03), (0.00, 0.16) | -0.00 (-0.07, 0.07) |
| Biliary colic | 1 (0.02) | 1 (0.03) | -0.00 (-0.07, 0.07) |
| Cholelithiasis | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Surgical and medical procedures | 1 (0.02), (0.00, 0.12) | 4 (0.12), (0.03, 0.30) | -0.10 (-0.23, 0.02) |
| Tooth extraction | 1 (0.02) | 1 (0.03) | -0.01 (-0.07, 0.05) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

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**Table 13.1.2 Subgroup Summary of Unsolicited Adverse Events Reported from Day 0 to 49 (28 Days Post Dose 2) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Cataract operation | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Spinal fusion surgery | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| Umbilical hernia repair | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Product issues | 0 (0.00), (0.00, 0.08) | 1 (0.03), (0.00, 0.16) | -0.03 (-0.08, 0.02) |
| Device occlusion | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 28.1.1 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 25282 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Total follow-up time (person-years) | 6337.9 | 4074.4 | |
| Average follow-up time (days) | 91.6 | 90.6 | |
| Median follow-up time (days) | 93 | 92 | |
| Any SAEs | 208 (3.28), (2.85, 3.76) | 144 (3.53), (2.98, 4.16) | -0.71 (-1.46, 0.04) |
| Infections and infestations | 35 (0.55), (0.38, 0.77) | 41 (1.01), (0.72, 1.37) | -0.53 (-0.91, -0.16) |
| Appendicitis | 6 (0.09) | 6 (0.15) | -0.06 (-0.21, 0.09) |
| COVID-19 | 4 (0.06) | 9 (0.22) | -0.19 (-0.36, -0.01) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t28_1_1.rtf. Generated from t_ser_sum_sub.sas 18JUL2021 20:59

**Table 28.1.1 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 25282 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Appendicitis perforated | 2 (0.03) | 1 (0.02) | 0.01 (-0.07, 0.08) |
| Pneumonia | 2 (0.03) | 1 (0.02) | -0.00 (-0.07, 0.07) |
| Abscess limb | 1 (0.02) | 1 (0.02) | -0.01 (-0.08, 0.05) |
| Arthritis bacterial | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| COVID-19 pneumonia | 1 (0.02) | 10 (0.25) | -0.22 (-0.38, -0.07) |
| Cellulitis | 1 (0.02) | 1 (0.02) | -0.01 (-0.08, 0.05) |
| Empyema | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t28_1_1.rtf. Generated from t_ser_sum_sub.sas 18JUL2021 20:59

**Table 28.1.1 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 25282 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Localised infection | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Mastitis | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Necrotising soft tissue infection | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Osteomyelitis | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Perineal abscess | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Pharyngeal abscess | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |
| Post procedural infection | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 28.1.1 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 25282 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Postoperative wound infection | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |
| Pulmonary tuberculosis | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |
| Pyelonephritis | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Sepsis | 1 (0.02) | 1 (0.02) | -0.01 (-0.08, 0.05) |
| Septic shock | 1 (0.02) | 1 (0.02) | -0.01 (-0.08, 0.05) |
| Staphylococcal infection | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Subcutaneous abscess | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 28.1.1 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 25282 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Urosepsis | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Viral infection | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Abdominal wall abscess | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Diverticulitis | 0 (0.00) | 3 (0.07) | -0.08 (-0.17, 0.01) |
| Epiglottitis | 0 (0.00) | 1 (0.02) | -0.02 (-0.06, 0.02) |
| Gastroenteritis | 0 (0.00) | 1 (0.02) | -0.02 (-0.06, 0.02) |
| Groin abscess | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 25282 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Lung abscess | 0 (0.00) | 1 (0.02) | -0.02 (-0.06, 0.02) |
| Otitis externa | 0 (0.00) | 1 (0.02) | -0.02 (-0.06, 0.02) |
| Pneumonia fungal | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Injury, poisoning and procedural complications | 28 (0.44), (0.29, 0.64) | 18 (0.44), (0.26, 0.70) | -0.03 (-0.31, 0.25) |
| Ankle fracture | 4 (0.06) | 0 (0.00) | 0.08 (0.00, 0.15) |
| Alcohol poisoning | 2 (0.03) | 1 (0.02) | -0.00 (-0.07, 0.07) |
| Accidental overdose | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 25282 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Burns third degree | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Concussion | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Facial bones fracture | 1 (0.02) | 1 (0.02) | -0.00 (-0.06, 0.06) |
| Fall | 1 (0.02) | 2 (0.05) | -0.04 (-0.11, 0.04) |
| Femur fracture | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |
| Fibula fracture | 1 (0.02) | 1 (0.02) | -0.01 (-0.08, 0.05) |
| Gun shot wound | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 25282 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Incisional hernia | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Intentional overdose | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |
| Limb injury | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |
| Overdose | 1 (0.02) | 3 (0.07) | -0.06 (-0.16, 0.03) |
| Radius fracture | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Rib fracture | 1 (0.02) | 1 (0.02) | -0.01 (-0.08, 0.05) |
| Skin laceration | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |

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|---|---|---|---|
| Snake bite | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Spinal fracture | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Splenic rupture | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Stab wound | 1 (0.02) | 1 (0.02) | -0.00 (-0.06, 0.06) |
| Tibia fracture | 1 (0.02) | 1 (0.02) | -0.01 (-0.08, 0.05) |
| Traumatic haematoma | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Wrist fracture | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |

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|---|---|---|---|
| Femoral neck fracture | 0 (0.00) | 1 (0.02) | -0.02 (-0.06, 0.02) |
| Foot fracture | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Foreign body in gastrointestinal tract | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Injury | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Joint injury | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Lumbar vertebral fracture | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Road traffic accident | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |

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|---|---|---|---|
| Cardiac disorders | 20 (0.32), (0.19, 0.49) | 12 (0.29), (0.15, 0.51) | -0.03 (-0.26, 0.19) |
| Atrial fibrillation | 5 (0.08) | 1 (0.02) | 0.04 (-0.04, 0.12) |
| Acute myocardial infarction | 2 (0.03) | 1 (0.02) | -0.00 (-0.07, 0.07) |
| Cardiac arrest | 2 (0.03) | 3 (0.07) | -0.06 (-0.16, 0.04) |
| Myocardial infarction | 2 (0.03) | 1 (0.02) | -0.00 (-0.07, 0.07) |
| Acute coronary syndrome | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |
| Acute left ventricular failure | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |

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|---|---|---|---|
| Angina pectoris | 1 (0.02) | 1 (0.02) | -0.01 (-0.06, 0.04) |
| Atrioventricular block complete | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |
| Cardiac failure congestive | 1 (0.02) | 1 (0.02) | -0.01 (-0.08, 0.05) |
| Cardiac pseudoaneurysm | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Coronary artery disease | 1 (0.02) | 1 (0.02) | -0.01 (-0.08, 0.05) |
| Myocarditis | 1 (0.02) | 1 (0.02) | -0.01 (-0.08, 0.06) |
| Palpitations | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |

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|---|---|---|---|
| Atrial flutter | 0 (0.00) | 1 (0.02) | -0.02 (-0.06, 0.02) |
| Cardio-respiratory arrest | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Nervous system disorders | 20 (0.32), (0.19, 0.49) | 13 (0.32), (0.17, 0.55) | -0.04 (-0.27, 0.19) |
| Cerebrovascular accident | 5 (0.08) | 0 (0.00) | 0.07 (0.01, 0.13) |
| Migraine | 2 (0.03) | 0 (0.00) | 0.04 (-0.02, 0.10) |
| Presyncope | 2 (0.03) | 0 (0.00) | 0.03 (-0.01, 0.08) |
| Seizure | 2 (0.03) | 1 (0.02) | -0.00 (-0.07, 0.07) |

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|---|---|---|---|
| Alcoholic seizure | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Altered state of consciousness | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Central nervous system inflammation | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Cervicogenic headache | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Ischaemic stroke | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Neuropathy peripheral | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Peroneal nerve palsy | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |

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|---|---|---|---|
| Sciatica | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |
| Transient ischaemic attack | 1 (0.02) | 2 (0.05) | -0.04 (-0.11, 0.04) |
| Carotid artery stenosis | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Cerebellar infarction | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Epilepsy | 0 (0.00) | 1 (0.02) | -0.02 (-0.06, 0.02) |
| Generalised tonic-clonic seizure | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Hypoaesthesia | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |

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|---|---|---|---|
| Lumbar radiculopathy | 0 (0.00) | 1 (0.02) | -0.02 (-0.06, 0.02) |
| Migraine with aura | 0 (0.00) | 1 (0.02) | -0.02 (-0.06, 0.02) |
| Multiple sclerosis | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Syncope | 0 (0.00) | 2 (0.05) | -0.06 (-0.13, 0.02) |
| Gastrointestinal disorders | 17 (0.27), (0.16, 0.43) | 5 (0.12), (0.04, 0.29) | 0.11 (-0.06, 0.28) |
| Intestinal obstruction | 2 (0.03) | 0 (0.00) | 0.03 (-0.01, 0.06) |
| Abdominal pain | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |

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|---|---|---|---|
| Alcoholic pancreatitis | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Ascites | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Colitis | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Gastritis | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Gastrooesophageal reflux disease | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |
| Haematemesis | 1 (0.02) | 1 (0.02) | -0.01 (-0.08, 0.05) |
| Hiatus hernia | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |

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|---|---|---|---|
| Impaired gastric emptying | 1 (0.02) | 1 (0.02) | -0.01 (-0.08, 0.05) |
| Mallory-Weiss syndrome | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Pancreatitis | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Pancreatitis acute | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Peptic ulcer | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Rectal haemorrhage | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Upper gastrointestinal haemorrhage | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |

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|---|---|---|---|
| Duodenal ulcer | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Gastric haemorrhage | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Gastritis erosive | 0 (0.00) | 1 (0.02) | -0.02 (-0.06, 0.02) |
| Hepatobiliary disorders | 12 (0.19), (0.10, 0.33) | 0 (0.00), (NA, 0.09) | 0.17 (0.07, 0.26) |
| Cholecystitis acute | 5 (0.08) | 0 (0.00) | 0.07 (0.01, 0.13) |
| Cholecystitis | 3 (0.05) | 0 (0.00) | 0.05 (-0.01, 0.10) |
| Bile duct stone | 2 (0.03) | 0 (0.00) | 0.03 (-0.01, 0.06) |

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|---|---|---|---|
| Cholelithiasis | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Cirrhosis alcoholic | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Psychiatric disorders | 12 (0.19), (0.10, 0.33) | 8 (0.20), (0.08, 0.39) | -0.05 (-0.23, 0.13) |
| Suicidal ideation | 3 (0.05) | 2 (0.05) | -0.02 (-0.11, 0.07) |
| Bipolar disorder | 2 (0.03) | 0 (0.00) | 0.03 (-0.01, 0.06) |
| Depression | 2 (0.03) | 1 (0.02) | -0.00 (-0.07, 0.06) |
| Acute psychosis | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |

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|---|---|---|---|
| Drug abuse | 1 (0.02) | 1 (0.02) | -0.01 (-0.08, 0.05) |
| Homicidal ideation | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Psychiatric symptom | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Substance abuse | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Alcohol abuse | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Delusion | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Panic attack | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |

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|---|---|---|---|
| Schizophrenia | 0 (0.00) | 1 (0.02) | -0.02 (-0.06, 0.02) |
| Respiratory, thoracic and mediastinal disorders | 12 (0.19), (0.10, 0.33) | 7 (0.17), (0.07, 0.35) | -0.01 (-0.18, 0.15) |
| Pneumonia aspiration | 3 (0.05) | 0 (0.00) | 0.04 (-0.01, 0.09) |
| Dyspnoea | 2 (0.03) | 1 (0.02) | -0.00 (-0.07, 0.07) |
| Pulmonary embolism | 2 (0.03) | 2 (0.05) | -0.01 (-0.10, 0.07) |
| Acute respiratory failure | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Asthma | 1 (0.02) | 1 (0.02) | -0.01 (-0.08, 0.05) |

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|---|---|---|---|
| Chronic obstructive pulmonary disease | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Pulmonary hypertension | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Respiratory failure | 1 (0.02) | 1 (0.02) | -0.01 (-0.08, 0.05) |
| Cough | 0 (0.00) | 1 (0.02) | -0.02 (-0.06, 0.02) |
| Pneumothorax | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 11 (0.17), (0.09, 0.31) | 6 (0.15), (0.05, 0.32) | 0.01 (-0.15, 0.18) |
| Breast cancer | 3 (0.05) | 0 (0.00) | 0.05 (-0.01, 0.10) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

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**Table 28.1.1 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 25282 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Prostate cancer | 2 (0.03) | 0 (0.00) | 0.03 (-0.01, 0.06) |
| Bladder cancer | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |
| Breast cancer stage III | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Cervix carcinoma | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |
| Chronic myeloid leukaemia | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Malignant melanoma | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Testis cancer | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 25282 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Anal squamous cell carcinoma | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Endometrial adenocarcinoma | 0 (0.00) | 2 (0.05) | -0.06 (-0.13, 0.02) |
| Intraductal proliferative breast lesion | 0 (0.00) | 1 (0.02) | -0.02 (-0.06, 0.02) |
| Invasive ductal breast carcinoma | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Rectal adenocarcinoma | 0 (0.00) | 1 (0.02) | -0.02 (-0.06, 0.02) |
| Vascular disorders | 8 (0.13), (0.05, 0.25) | 5 (0.12), (0.04, 0.29) | -0.03 (-0.17, 0.11) |
| Hypertension | 3 (0.05) | 1 (0.02) | 0.02 (-0.04, 0.08) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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|---|---|---|---|
| Hypotension | 2 (0.03) | 1 (0.02) | -0.00 (-0.07, 0.07) |
| Circulatory collapse | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Hypertensive crisis | 1 (0.02) | 2 (0.05) | -0.04 (-0.13, 0.04) |
| Intermittent claudication | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Embolism | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Pregnancy, puerperium and perinatal conditions | 6 (0.09), (0.03, 0.21) | 2 (0.05), (0.01, 0.18) | 0.04 (-0.06, 0.14) |
| Abortion spontaneous | 3 (0.05) | 1 (0.02) | 0.02 (-0.06, 0.10) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 25282 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Pregnancy | 2 (0.03) | 0 (0.00) | 0.03 (-0.01, 0.06) |
| Abortion spontaneous complete | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Hyperemesis gravidarum | 0 (0.00) | 1 (0.02) | -0.02 (-0.06, 0.02) |
| Blood and lymphatic system disorders | 5 (0.08), (0.03, 0.18) | 2 (0.05), (0.01, 0.18) | 0.03 (-0.07, 0.12) |
| Anaemia | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |
| Blood loss anaemia | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Iron deficiency anaemia | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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|---|---|---|---|
| Normocytic anaemia | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Thrombocytopenia | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Haemolytic anaemia | 0 (0.00) | 1 (0.02) | -0.02 (-0.06, 0.02) |
| Leukocytosis | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| General disorders and administration site conditions | 3 (0.05), (0.01, 0.14) | 4 (0.10), (0.03, 0.25) | -0.07 (-0.19, 0.05) |
| Chest pain | 1 (0.02) | 2 (0.05) | -0.04 (-0.13, 0.04) |
| Drug withdrawal syndrome | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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|---|---|---|---|
| Sudden death | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Catheter site thrombosis | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Oedema peripheral | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Metabolism and nutrition disorders | 3 (0.05), (0.01, 0.14) | 8 (0.20), (0.08, 0.39) | -0.18 (-0.34, -0.02) |
| Diabetic ketoacidosis | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Electrolyte imbalance | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Type 2 diabetes mellitus | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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|---|---|---|---|
| Dehydration | 0 (0.00) | 2 (0.05) | -0.06 (-0.13, 0.02) |
| Diabetic ketosis | 0 (0.00) | 1 (0.02) | -0.02 (-0.06, 0.02) |
| Hyperglycaemia | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Hypoglycaemia | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Hypokalaemia | 0 (0.00) | 2 (0.05) | -0.06 (-0.13, 0.02) |
| Hyponatraemia | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Musculoskeletal and connective tissue disorders | 3 (0.05), (0.01, 0.14) | 3 (0.07), (0.02, 0.22) | -0.04 (-0.14, 0.06) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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|---|---|---|---|
| Arthralgia | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Intervertebral disc protrusion | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Rhabdomyolysis | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Intervertebral disc disorder | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Musculoskeletal pain | 0 (0.00) | 1 (0.02) | -0.02 (-0.06, 0.02) |
| Neck pain | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Endocrine disorders | 2 (0.03), (0.00, 0.11) | 0 (0.00), (NA, 0.09) | 0.03 (-0.01, 0.06) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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|---|---|---|---|
| Basedow's disease | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Hyperthyroidism | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Renal and urinary disorders | 2 (0.03), (0.00, 0.11) | 6 (0.15), (0.05, 0.32) | -0.12 (-0.25, 0.00) |
| Acute kidney injury | 1 (0.02) | 1 (0.02) | -0.01 (-0.08, 0.05) |
| Nephrolithiasis | 1 (0.02) | 3 (0.07) | -0.06 (-0.16, 0.03) |
| Nephrotic syndrome | 0 (0.00) | 1 (0.02) | -0.02 (-0.06, 0.02) |
| Urethral dilatation | 0 (0.00) | 1 (0.02) | -0.02 (-0.06, 0.02) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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|---|---|---|---|
| Reproductive system and breast disorders | 2 (0.03), (0.00, 0.11) | 0 (0.00), (NA, 0.09) | 0.04 (-0.02, 0.10) |
| Endometriosis | 2 (0.03) | 0 (0.00) | 0.04 (-0.02, 0.10) |
| Skin and subcutaneous tissue disorders | 2 (0.03), (0.00, 0.11) | 0 (0.00), (NA, 0.09) | 0.03 (-0.01, 0.06) |
| Angioedema | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Skin ulcer | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Surgical and medical procedures | 2 (0.03), (0.00, 0.11) | 1 (0.02), (0.00, 0.14) | 0.01 (-0.07, 0.08) |
| Cholecystectomy | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

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**Table 28.1.1 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 25282 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Coronary arterial stent insertion | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Hip arthroplasty | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Eye disorders | 1 (0.02), (0.00, 0.09) | 0 (0.00), (NA, 0.09) | 0.01 (-0.01, 0.04) |
| Diplopia | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Social circumstances | 1 (0.02), (0.00, 0.09) | 0 (0.00), (NA, 0.09) | 0.02 (-0.02, 0.06) |
| Physical assault | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |
| Uncoded | 1 (0.02), (0.00, 0.09) | 1 (0.02), (0.00, 0.14) | -0.01 (-0.06, 0.04) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

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**Table 28.1.1 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 25282 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| CHOLECYSTITIS AND CHOLELITHIASIS | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Uncoded | 0 (0.00) | 1 (0.02) | -0.02 (-0.06, 0.02) |
| Investigations | 0 (0.00), (NA, 0.06) | 2 (0.05), (0.01, 0.18) | -0.06 (-0.13, 0.02) |
| Oxygen saturation decreased | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| SARS-CoV-2 test positive | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 28.1.2 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 4776 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Total follow-up time (person-years) | 1127.1 | 802.8 | |
| Average follow-up time (days) | 86.2 | 84.8 | |
| Median follow-up time (days) | 91 | 88 | |
| Any SAEs | 76 (6.74), (5.31, 8.44) | 53 (6.60), (4.95, 8.64) | -0.67 (-3.04, 1.69) |
| Cardiac disorders | 15 (1.33), (0.74, 2.19) | 7 (0.87), (0.35, 1.80) | 0.29 (-0.65, 1.23) |
| Acute left ventricular failure | 2 (0.18) | 0 (0.00) | 0.14 (-0.05, 0.33) |
| Acute myocardial infarction | 2 (0.18) | 1 (0.12) | 0.04 (-0.36, 0.43) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t28_1_2.rtf. Generated from t_ser_sum_sub.sas 18JUL2021 20:59

**Table 28.1.2 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 4776 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Atrial fibrillation | 2 (0.18) | 2 (0.25) | -0.12 (-0.54, 0.29) |
| Cardiac failure congestive | 2 (0.18) | 0 (0.00) | 0.14 (-0.05, 0.33) |
| Atrial tachycardia | 1 (0.09) | 0 (0.00) | 0.11 (-0.11, 0.32) |
| Cardiac arrest | 1 (0.09) | 0 (0.00) | 0.07 (-0.07, 0.21) |
| Cardiac failure acute | 1 (0.09) | 0 (0.00) | 0.11 (-0.11, 0.32) |
| Myocardial infarction | 1 (0.09) | 1 (0.12) | -0.08 (-0.41, 0.24) |
| Myocarditis | 1 (0.09) | 0 (0.00) | 0.07 (-0.07, 0.21) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t28_1_2.rtf. Generated from t_ser_sum_sub.sas 18JUL2021 20:59

**Table 28.1.2 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 4776 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Palpitations | 1 (0.09) | 0 (0.00) | 0.11 (-0.11, 0.32) |
| Sinus node dysfunction | 1 (0.09) | 0 (0.00) | 0.08 (-0.07, 0.23) |
| Arrhythmia | 0 (0.00) | 1 (0.12) | -0.11 (-0.33, 0.11) |
| Atrioventricular block complete | 0 (0.00) | 1 (0.12) | -0.11 (-0.33, 0.11) |
| Coronary artery disease | 0 (0.00) | 1 (0.12) | -0.15 (-0.45, 0.14) |
| Injury, poisoning and procedural complications | 12 (1.06), (0.55, 1.86) | 3 (0.37), (0.08, 1.09) | 0.67 (-0.07, 1.40) |
| Femur fracture | 2 (0.18) | 0 (0.00) | 0.14 (-0.05, 0.33) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 28.1.2 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 4776 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Cervical vertebral fracture | 1 (0.09) | 0 (0.00) | 0.11 (-0.11, 0.32) |
| Exposure to toxic agent | 1 (0.09) | 0 (0.00) | 0.07 (-0.07, 0.21) |
| Hip fracture | 1 (0.09) | 0 (0.00) | 0.07 (-0.07, 0.21) |
| Jaw fracture | 1 (0.09) | 0 (0.00) | 0.07 (-0.07, 0.21) |
| Joint dislocation | 1 (0.09) | 0 (0.00) | 0.11 (-0.11, 0.32) |
| Poisoning deliberate | 1 (0.09) | 0 (0.00) | 0.11 (-0.11, 0.32) |
| Radius fracture | 1 (0.09) | 0 (0.00) | 0.11 (-0.11, 0.32) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 28.1.2 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 4776 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Rib fracture | 1 (0.09) | 0 (0.00) | 0.07 (-0.07, 0.21) |
| Ulna fracture | 1 (0.09) | 0 (0.00) | 0.11 (-0.11, 0.32) |
| Wrist fracture | 1 (0.09) | 1 (0.12) | -0.04 (-0.30, 0.22) |
| Fall | 0 (0.00) | 1 (0.12) | -0.15 (-0.45, 0.14) |
| Femoral neck fracture | 0 (0.00) | 1 (0.12) | -0.11 (-0.33, 0.11) |
| Infections and infestations | 11 (0.98), (0.49, 1.75) | 14 (1.74), (0.95, 2.93) | -0.90 (-2.02, 0.22) |
| COVID-19 | 4 (0.35) | 2 (0.25) | 0.10 (-0.41, 0.61) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 28.1.2 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 4776 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Pneumonia | 2 (0.18) | 4 (0.50) | -0.34 (-0.86, 0.17) |
| Appendicitis | 1 (0.09) | 1 (0.12) | -0.04 (-0.30, 0.22) |
| Cellulitis | 1 (0.09) | 1 (0.12) | -0.08 (-0.41, 0.24) |
| Intestinal gangrene | 1 (0.09) | 0 (0.00) | 0.11 (-0.11, 0.32) |
| Sepsis | 1 (0.09) | 1 (0.12) | -0.08 (-0.41, 0.24) |
| Wound infection | 1 (0.09) | 0 (0.00) | 0.11 (-0.11, 0.32) |
| Arthritis bacterial | 0 (0.00) | 1 (0.12) | -0.15 (-0.45, 0.14) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 28.1.2 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 4776 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Bacterial sepsis | 0 (0.00) | 1 (0.12) | -0.11 (-0.33, 0.11) |
| COVID-19 pneumonia | 0 (0.00) | 2 (0.25) | -0.26 (-0.63, 0.10) |
| Streptococcal bacteraemia | 0 (0.00) | 1 (0.12) | -0.15 (-0.45, 0.14) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 8 (0.71), (0.31, 1.40) | 5 (0.62), (0.20, 1.45) | 0.09 (-0.61, 0.80) |
| Prostate cancer | 3 (0.27) | 0 (0.00) | 0.21 (-0.03, 0.45) |
| Breast cancer | 1 (0.09) | 0 (0.00) | 0.11 (-0.11, 0.32) |
| Breast cancer metastatic | 1 (0.09) | 0 (0.00) | 0.07 (-0.07, 0.21) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

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**Table 28.1.2 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 4776 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Lung neoplasm malignant | 1 (0.09) | 0 (0.00) | 0.11 (-0.11, 0.32) |
| Non-Hodgkin's lymphoma | 1 (0.09) | 1 (0.12) | -0.07 (-0.38, 0.24) |
| Squamous cell carcinoma of skin | 1 (0.09) | 0 (0.00) | 0.11 (-0.11, 0.32) |
| Adenocarcinoma of appendix | 0 (0.00) | 1 (0.12) | -0.11 (-0.33, 0.11) |
| Glioblastoma | 0 (0.00) | 1 (0.12) | -0.11 (-0.33, 0.11) |
| Ovarian cancer | 0 (0.00) | 1 (0.12) | -0.11 (-0.33, 0.11) |
| Squamous cell carcinoma of the tongue | 0 (0.00) | 1 (0.12) | -0.11 (-0.33, 0.11) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 28.1.2 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 4776 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| General disorders and administration site conditions | 5 (0.44), (0.14, 1.04) | 2 (0.25), (0.03, 0.90) | 0.13 (-0.44, 0.70) |
| Asthenia | 2 (0.18) | 0 (0.00) | 0.14 (-0.05, 0.33) |
| Death | 1 (0.09) | 0 (0.00) | 0.11 (-0.11, 0.33) |
| Mass | 1 (0.09) | 0 (0.00) | 0.11 (-0.11, 0.32) |
| Oedema peripheral | 1 (0.09) | 0 (0.00) | 0.07 (-0.07, 0.21) |
| Chest pain | 0 (0.00) | 1 (0.12) | -0.15 (-0.45, 0.14) |
| Oedema | 0 (0.00) | 1 (0.12) | -0.15 (-0.45, 0.14) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 28.1.2 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 4776 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Respiratory, thoracic and mediastinal disorders | 5 (0.44), (0.14, 1.04) | 4 (0.50), (0.14, 1.28) | -0.21 (-0.85, 0.42) |
| Acute respiratory failure | 2 (0.18) | 0 (0.00) | 0.14 (-0.05, 0.33) |
| Pulmonary embolism | 2 (0.18) | 1 (0.12) | -0.01 (-0.36, 0.34) |
| Chronic obstructive pulmonary disease | 1 (0.09) | 0 (0.00) | 0.07 (-0.07, 0.21) |
| Asthma | 0 (0.00) | 1 (0.12) | -0.15 (-0.45, 0.14) |
| Dyspnoea | 0 (0.00) | 1 (0.12) | -0.15 (-0.45, 0.14) |
| Epistaxis | 0 (0.00) | 1 (0.12) | -0.11 (-0.33, 0.11) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 28.1.2 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 4776 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Renal and urinary disorders | 4 (0.35), (0.10, 0.91) | 2 (0.25), (0.03, 0.90) | 0.10 (-0.42, 0.61) |
| Acute kidney injury | 2 (0.18) | 1 (0.12) | 0.07 (-0.27, 0.40) |
| Chronic kidney disease | 1 (0.09) | 0 (0.00) | 0.07 (-0.07, 0.21) |
| Urinary retention | 1 (0.09) | 0 (0.00) | 0.11 (-0.11, 0.32) |
| Renal failure | 0 (0.00) | 1 (0.12) | -0.15 (-0.45, 0.14) |
| Vascular disorders | 4 (0.35), (0.10, 0.91) | 1 (0.12), (0.00, 0.69) | 0.17 (-0.18, 0.52) |
| Deep vein thrombosis | 2 (0.18) | 0 (0.00) | 0.14 (-0.05, 0.33) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 28.1.2 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 4776 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Arterial occlusive disease | 1 (0.09) | 0 (0.00) | 0.07 (-0.07, 0.21) |
| Haematoma | 1 (0.09) | 0 (0.00) | 0.07 (-0.07, 0.21) |
| Peripheral ischaemia | 0 (0.00) | 1 (0.12) | -0.11 (-0.33, 0.11) |
| Musculoskeletal and connective tissue disorders | 3 (0.27), (0.05, 0.78) | 0 (0.00), (NA, 0.46) | 0.21 (-0.03, 0.45) |
| Intervertebral disc protrusion | 1 (0.09) | 0 (0.00) | 0.07 (-0.07, 0.21) |
| Osteoarthritis | 1 (0.09) | 0 (0.00) | 0.07 (-0.07, 0.21) |
| Osteolysis | 1 (0.09) | 0 (0.00) | 0.07 (-0.07, 0.21) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 28.1.2 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 4776 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Nervous system disorders | 3 (0.27), (0.05, 0.78) | 1 (0.12), (0.00, 0.69) | 0.06 (-0.32, 0.44) |
| Cerebrovascular accident | 2 (0.18) | 1 (0.12) | -0.01 (-0.36, 0.34) |
| Ischaemic stroke | 1 (0.09) | 0 (0.00) | 0.07 (-0.07, 0.21) |
| Gastrointestinal disorders | 2 (0.18), (0.02, 0.64) | 5 (0.62), (0.20, 1.45) | -0.49 (-1.09, 0.10) |
| Colitis ulcerative | 1 (0.09) | 0 (0.00) | 0.07 (-0.07, 0.21) |
| Gastrointestinal haemorrhage | 1 (0.09) | 0 (0.00) | 0.07 (-0.07, 0.21) |
| Intestinal perforation | 0 (0.00) | 1 (0.12) | -0.11 (-0.33, 0.11) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 28.1.2 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 4776 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Nausea | 0 (0.00) | 1 (0.12) | -0.15 (-0.45, 0.14) |
| Obstructive pancreatitis | 0 (0.00) | 1 (0.12) | -0.11 (-0.33, 0.11) |
| Small intestinal obstruction | 0 (0.00) | 1 (0.12) | -0.11 (-0.33, 0.11) |
| Vomiting | 0 (0.00) | 1 (0.12) | -0.15 (-0.45, 0.14) |
| Ear and labyrinth disorders | 1 (0.09), (0.00, 0.49) | 0 (0.00), (NA, 0.46) | 0.08 (-0.07, 0.23) |
| Vertigo | 1 (0.09) | 0 (0.00) | 0.08 (-0.07, 0.23) |
| Metabolism and nutrition disorders | 1 (0.09), (0.00, 0.49) | 1 (0.12), (0.00, 0.69) | -0.00 (-0.31, 0.30) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

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**Table 28.1.2 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 4776 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Dehydration | 1 (0.09) | 0 (0.00) | 0.11 (-0.11, 0.32) |
| Hypoalbuminaemia | 0 (0.00) | 1 (0.12) | -0.11 (-0.33, 0.11) |
| Reproductive system and breast disorders | 1 (0.09), (0.00, 0.49) | 1 (0.12), (0.00, 0.69) | -0.04 (-0.41, 0.32) |
| Vaginal prolapse | 1 (0.09) | 0 (0.00) | 0.11 (-0.11, 0.32) |
| Benign prostatic hyperplasia | 0 (0.00) | 1 (0.12) | -0.15 (-0.45, 0.14) |
| Skin and subcutaneous tissue disorders | 1 (0.09), (0.00, 0.49) | 0 (0.00), (NA, 0.46) | 0.07 (-0.07, 0.21) |
| Dermatitis | 1 (0.09) | 0 (0.00) | 0.07 (-0.07, 0.21) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

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**Table 28.1.2 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 4776 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Blood and lymphatic system disorders | 0 (0.00), (NA, 0.33) | 2 (0.25), (0.03, 0.90) | -0.22 (-0.53, 0.09) |
| Anaemia | 0 (0.00) | 1 (0.12) | -0.11 (-0.33, 0.11) |
| Iron deficiency anaemia | 0 (0.00) | 1 (0.12) | -0.11 (-0.33, 0.11) |
| Hepatobiliary disorders | 0 (0.00), (NA, 0.33) | 1 (0.12), (0.00, 0.69) | -0.11 (-0.33, 0.11) |
| Liver injury | 0 (0.00) | 1 (0.12) | -0.11 (-0.33, 0.11) |
| Investigations | 0 (0.00), (NA, 0.33) | 1 (0.12), (0.00, 0.69) | -0.11 (-0.33, 0.11) |
| Blood pressure systolic increased | 0 (0.00) | 1 (0.12) | -0.11 (-0.33, 0.11) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

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**Table 28.1.2 Subgroup Summary of Event Rates of Serious Adverse Events Reported During the Study (from Day 0 to End of Follow-up) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 4776 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Psychiatric disorders | 0 (0.00), (NA, 0.33) | 2 (0.25), (0.03, 0.90) | -0.30 (-0.72, 0.12) |
| Bipolar disorder | 0 (0.00) | 1 (0.12) | -0.15 (-0.45, 0.14) |
| Suicidal ideation | 0 (0.00) | 1 (0.12) | -0.15 (-0.45, 0.14) |
| Surgical and medical procedures | 0 (0.00), (NA, 0.33) | 1 (0.12), (0.00, 0.69) | -0.15 (-0.45, 0.14) |
| Spinal fusion surgery | 0 (0.00) | 1 (0.12) | -0.15 (-0.45, 0.14) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 31.1.1.a Subgroup Summary of Death Events Reported During the Study (from Day 0 to End of Follow-up) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Any unsolicited AEs | 7 (0.03), (0.01, 0.06) | 5 (0.03), (0.01, 0.07) | -0.01 (-0.04, 0.03) |
| Cardiac disorders | 2 (<0.01), (0.00, 0.03) | 3 (0.02), (0.00, 0.05) | -0.01 (-0.04, 0.01) |
| Cardiac arrest | 2 (<0.01) | 3 (0.02) | -0.01 (-0.04, 0.01) |
| Infections and infestations | 2 (<0.01), (0.00, 0.03) | 2 (0.01), (0.00, 0.04) | -0.00 (-0.02, 0.02) |
| COVID-19 pneumonia | 1 (<0.01) | 0 (0.00) | 0.01 (-0.00, 0.02) |
| Septic shock | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| COVID-19 | 0 (0.00) | 2 (0.01) | -0.01 (-0.03, 0.00) |
| General disorders and administration site conditions | 1 (<0.01), (0.00, 0.02) | 0 (0.00), (0.00, 0.02) | 0.00 (-0.00, 0.01) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

File Name: t31_1_1_a.rtf. Generated from t_death_soc_sub.sas 29JUL2021 18:33

**Table 31.1.1.a Subgroup Summary of Death Events Reported During the Study (from Day 0 to End of Follow-up) by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 25282 | Placebo<br>(n, %, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Sudden death | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Injury, poisoning and procedural complications | 1 (<0.01), (0.00, 0.02) | 0 (0.00), (0.00, 0.02) | 0.00 (-0.00, 0.01) |
| Gun shot wound | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |
| Vascular disorders | 1 (<0.01), (0.00, 0.02) | 0 (0.00), (0.00, 0.02) | 0.00 (-0.00, 0.01) |
| Circulatory collapse | 1 (<0.01) | 0 (0.00) | 0.00 (-0.00, 0.01) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
File Name: t31_1_1_a.rtf. Generated from t_death_soc_sub.sas 29JUL2021 18:33

**Table 31.1.2.a Subgroup Summary of Death Events Reported During the Study (from Day 0 to End of Follow-up) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Any unsolicited AEs | 5 (0.10), (0.03, 0.24) | 3 (0.09), (0.02, 0.25) | 0.03 (-0.11, 0.16) |
| Cardiac disorders | 1 (0.02), (0.00, 0.12) | 1 (0.03), (0.00, 0.16) | -0.02 (-0.09, 0.06) |
| Cardiac arrest | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Myocardial infarction | 0 (0.00) | 1 (0.03) | -0.03 (-0.10, 0.03) |
| General disorders and administration site conditions | 1 (0.02), (0.00, 0.12) | 0 (0.00), (0.00, 0.11) | 0.03 (-0.02, 0.08) |
| Death | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Infections and infestations | 1 (0.02), (0.00, 0.12) | 2 (0.06), (0.01, 0.21) | -0.03 (-0.11, 0.06) |
| COVID-19 | 1 (0.02) | 1 (0.03) | 0.00 (-0.07, 0.07) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

File Name: t31_1_2_a.rtf. Generated from t_death_soc_sub.sas 29JUL2021 18:33

**Table 31.1.2.a Subgroup Summary of Death Events Reported During the Study (from Day 0 to End of Follow-up) by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Subjects) | Vaccine<br>(n, %, 95% CI)<br>N = 4776 | Placebo<br>(n, %, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(%, 95% CI) |
|---|---|---|---|
| Bacterial sepsis | 0 (0.00) | 1 (0.03) | -0.03 (-0.08, 0.02) |
| Injury, poisoning and procedural complications | 1 (0.02), (0.00, 0.12) | 0 (0.00), (0.00, 0.11) | 0.03 (-0.02, 0.08) |
| Poisoning deliberate | 1 (0.02) | 0 (0.00) | 0.03 (-0.02, 0.08) |
| Nervous system disorders | 1 (0.02), (0.00, 0.12) | 0 (0.00), (0.00, 0.11) | 0.02 (-0.02, 0.05) |
| Cerebrovascular accident | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.05) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
File Name: t31_1_2_a.rtf. Generated from t_death_soc_sub.sas 29JUL2021 18:33

**Table 32 Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up)**
**Per Site Reported**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 30058 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 19892 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Total follow-up time (person-years) | 7465.0 | 4877.1 | |
| Average follow-up time (days) | 90.7 | 89.6 | |
| Median follow-up time (days) | 92 | 91 | |
| Any PIMMCs | 27 (0.36), (0.24, 0.53) | 9 (0.18), (0.08, 0.35) | 0.16 (-0.02, 0.34) |
| Musculoskeletal and connective tissue disorders | 6 (0.08), (0.03, 0.17) | 2 (0.04), (0.00, 0.15) | 0.06 (-0.03, 0.15) |
| Arthritis | 2 (0.03) | 0 (0.00) | 0.03 (-0.01, 0.07) |
| Polymyalgia rheumatica | 2 (0.03) | 1 (0.02) | 0.01 (-0.04, 0.06) |
| Psoriatic arthropathy | 1 (0.01) | 0 (0.00) | 0.02 (-0.02, 0.05) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t32.rtf. Generated from t_pimmc_sum_sub.sas 19JUL2021 12:55

**Table 32 Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up)**
**Per Site Reported**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 30058 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 19892 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Rheumatoid arthritis | 1 (0.01) | 1 (0.02) | -0.00 (-0.05, 0.05) |
| Nervous system disorders | 6 (0.08), (0.03, 0.17) | 3 (0.06), (0.01, 0.18) | -0.00 (-0.10, 0.09) |
| Central nervous system inflammation | 1 (0.01) | 0 (0.00) | 0.01 (-0.01, 0.03) |
| Hypoaesthesia | 1 (0.01) | 1 (0.02) | -0.01 (-0.06, 0.04) |
| Neuralgia | 1 (0.01) | 0 (0.00) | 0.01 (-0.01, 0.03) |
| Neuropathy peripheral | 1 (0.01) | 0 (0.00) | 0.01 (-0.01, 0.03) |
| Peroneal nerve palsy | 1 (0.01) | 0 (0.00) | 0.01 (-0.01, 0.03) |
| Seizure | 1 (0.01) | 1 (0.02) | -0.01 (-0.06, 0.04) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t32.rtf. Generated from t_pimmc_sum_sub.sas 19JUL2021 12:55

**Table 32 Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up)**
**Per Site Reported**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 30058 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 19892 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Multiple sclerosis | 0 (0.00) | 1 (0.02) | -0.02 (-0.07, 0.02) |
| Endocrine disorders | 4 (0.05), (0.01, 0.14) | 0 (0.00), (NA, 0.08) | 0.05 (0.00, 0.09) |
| Basedow's disease | 2 (0.03) | 0 (0.00) | 0.02 (-0.01, 0.05) |
| Autoimmune thyroiditis | 1 (0.01) | 0 (0.00) | 0.01 (-0.01, 0.03) |
| Hyperthyroidism | 1 (0.01) | 0 (0.00) | 0.01 (-0.01, 0.03) |
| Eye disorders | 4 (0.05), (0.01, 0.14) | 0 (0.00), (NA, 0.08) | 0.05 (0.00, 0.09) |
| Uveitis | 3 (0.04) | 0 (0.00) | 0.03 (-0.00, 0.07) |
| Iridocyclitis | 1 (0.01) | 0 (0.00) | 0.01 (-0.01, 0.03) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t32.rtf. Generated from t_pimmc_sum_sub.sas 19JUL2021 12:55

**Table 32 Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up)**
**Per Site Reported**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 30058 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 19892 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Skin and subcutaneous tissue disorders | 2 (0.03), (0.00, 0.10) | 2 (0.04), (0.00, 0.15) | -0.02 (-0.10, 0.06) |
| Alopecia areata | 1 (0.01) | 0 (0.00) | 0.01 (-0.01, 0.03) |
| Pemphigoid | 1 (0.01) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Lichen planus | 0 (0.00) | 1 (0.02) | -0.02 (-0.07, 0.02) |
| Lichenoid keratosis | 0 (0.00) | 1 (0.02) | -0.02 (-0.07, 0.02) |
| Blood and lymphatic system disorders | 1 (0.01), (0.00, 0.07) | 1 (0.02), (0.00, 0.11) | -0.01 (-0.05, 0.03) |
| Thrombocytopenia | 1 (0.01) | 1 (0.02) | -0.01 (-0.05, 0.03) |
| Cardiac disorders | 1 (0.01), (0.00, 0.07) | 0 (0.00), (NA, 0.08) | 0.02 (-0.02, 0.05) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t32.rtf. Generated from t_pimmc_sum_sub.sas 19JUL2021 12:55

**Table 32 Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up)**
**Per Site Reported**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 30058 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 19892 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Myocarditis | 1 (0.01) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Gastrointestinal disorders | 1 (0.01), (0.00, 0.07) | 1 (0.02), (0.00, 0.11) | -0.01 (-0.05, 0.03) |
| Colitis ulcerative | 1 (0.01) | 0 (0.00) | 0.01 (-0.01, 0.03) |
| Crohn's disease | 0 (0.00) | 1 (0.02) | -0.02 (-0.05, 0.02) |
| Injury, poisoning and procedural complications | 1 (0.01), (0.00, 0.07) | 0 (0.00), (NA, 0.08) | 0.02 (-0.02, 0.05) |
| Chillblains | 1 (0.01) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Investigations | 1 (0.01), (0.00, 0.07) | 0 (0.00), (NA, 0.08) | 0.01 (-0.01, 0.03) |
| Heparin-induced thrombocytopenia test | 1 (0.01) | 0 (0.00) | 0.01 (-0.01, 0.03) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t32.rtf. Generated from t_pimmc_sum_sub.sas 19JUL2021 12:55

**Table 37 Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up)**
**Per Protocol Defined Criteria**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 30058 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 19892 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Total follow-up time (person-years) | 7465.0 | 4877.1 | |
| Average follow-up time (days) | 90.7 | 89.6 | |
| Median follow-up time (days) | 92 | 91 | |
| Any PIMMCs | 30 (0.40), (0.27, 0.57) | 19 (0.39), (0.23, 0.61) | -0.04 (-0.27, 0.19) |
| Nervous system disorders | 9 (0.12), (0.06, 0.23) | 7 (0.14), (0.06, 0.30) | -0.05 (-0.19, 0.09) |
| Seizure | 4 (0.05) | 3 (0.06) | -0.03 (-0.12, 0.07) |
| Neuropathy peripheral | 3 (0.04) | 2 (0.04) | -0.01 (-0.09, 0.06) |
| Facial paralysis | 1 (0.01) | 1 (0.02) | -0.00 (-0.05, 0.05) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t37.rtf. Generated from t_pimmc_sum_sub.sas 19JUL2021 12:55

**Table 37 Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up)**
**Per Protocol Defined Criteria**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 30058 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 19892 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Narcolepsy | 1 (0.01) | 0 (0.00) | 0.01 (-0.01, 0.03) |
| Multiple sclerosis | 0 (0.00) | 1 (0.02) | -0.02 (-0.07, 0.02) |
| Skin and subcutaneous tissue disorders | 6 (0.08), (0.03, 0.17) | 1 (0.02), (0.00, 0.11) | 0.05 (-0.03, 0.13) |
| Alopecia areata | 2 (0.03) | 0 (0.00) | 0.02 (-0.01, 0.05) |
| Psoriasis | 2 (0.03) | 0 (0.00) | 0.02 (-0.01, 0.05) |
| Erythema nodosum | 1 (0.01) | 0 (0.00) | 0.01 (-0.01, 0.03) |
| Pemphigoid | 1 (0.01) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Lichen planus | 0 (0.00) | 1 (0.02) | -0.02 (-0.07, 0.02) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t37.rtf. Generated from t_pimmc_sum_sub.sas 19JUL2021 12:55

**Table 37 Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up)**
**Per Protocol Defined Criteria**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 30058 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 19892 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Musculoskeletal and connective tissue disorders | 5 (0.07), (0.02, 0.16) | 5 (0.10), (0.03, 0.24) | -0.03 (-0.14, 0.09) |
| Polymyalgia rheumatica | 2 (0.03) | 1 (0.02) | 0.01 (-0.04, 0.06) |
| Rheumatoid arthritis | 2 (0.03) | 3 (0.06) | -0.04 (-0.12, 0.05) |
| Psoriatic arthropathy | 1 (0.01) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Arthritis reactive | 0 (0.00) | 1 (0.02) | -0.02 (-0.05, 0.02) |
| Endocrine disorders | 3 (0.04), (0.01, 0.12) | 1 (0.02), (0.00, 0.11) | 0.01 (-0.05, 0.07) |
| Basedow's disease | 2 (0.03) | 0 (0.00) | 0.02 (-0.01, 0.05) |
| Autoimmune thyroiditis | 1 (0.01) | 1 (0.02) | -0.01 (-0.06, 0.04) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t37.rtf. Generated from t_pimmc_sum_sub.sas 19JUL2021 12:55

**Table 37 Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up)**
**Per Protocol Defined Criteria**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 30058 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 19892 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Eye disorders | 3 (0.04), (0.01, 0.12) | 1 (0.02), (0.00, 0.11) | 0.01 (-0.05, 0.07) |
| Uveitis | 3 (0.04) | 1 (0.02) | 0.01 (-0.05, 0.07) |
| Blood and lymphatic system disorders | 2 (0.03), (0.00, 0.10) | 2 (0.04), (0.00, 0.15) | -0.01 (-0.08, 0.06) |
| Thrombocytopenia | 2 (0.03) | 2 (0.04) | -0.01 (-0.08, 0.06) |
| Gastrointestinal disorders | 2 (0.03), (0.00, 0.10) | 2 (0.04), (0.00, 0.15) | -0.02 (-0.08, 0.05) |
| Colitis ulcerative | 1 (0.01) | 0 (0.00) | 0.01 (-0.01, 0.03) |
| Crohn's disease | 1 (0.01) | 1 (0.02) | -0.01 (-0.05, 0.03) |
| Coeliac disease | 0 (0.00) | 1 (0.02) | -0.02 (-0.07, 0.02) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

File Name: t37.rtf. Generated from t_pimmc_sum_sub.sas 19JUL2021 12:55

**Table 42 Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up)**
**Per Site Reported or Protocol Defined Criteria**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 30058 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 19892 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Total follow-up time (person-years) | 7465.0 | 4877.1 | |
| Average follow-up time (days) | 90.7 | 89.6 | |
| Median follow-up time (days) | 92 | 91 | |
| Any PIMMCs | 41 (0.55), (0.39, 0.75) | 21 (0.43), (0.27, 0.66) | 0.06 (-0.20, 0.31) |
| Nervous system disorders | 13 (0.17), (0.09, 0.30) | 8 (0.16), (0.07, 0.32) | -0.03 (-0.18, 0.12) |
| Seizure | 4 (0.05) | 3 (0.06) | -0.03 (-0.12, 0.07) |
| Neuropathy peripheral | 3 (0.04) | 2 (0.04) | -0.01 (-0.09, 0.06) |
| Central nervous system inflammation | 1 (0.01) | 0 (0.00) | 0.01 (-0.01, 0.03) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t42.rtf. Generated from t_pimmc_sum_sub.sas 19JUL2021 12:55

**Table 42 Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up)**
**Per Site Reported or Protocol Defined Criteria**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 30058 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 19892 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Facial paralysis | 1 (0.01) | 1 (0.02) | -0.00 (-0.05, 0.05) |
| Hypoaesthesia | 1 (0.01) | 1 (0.02) | -0.01 (-0.06, 0.04) |
| Narcolepsy | 1 (0.01) | 0 (0.00) | 0.01 (-0.01, 0.03) |
| Neuralgia | 1 (0.01) | 0 (0.00) | 0.01 (-0.01, 0.03) |
| Peroneal nerve palsy | 1 (0.01) | 0 (0.00) | 0.01 (-0.01, 0.03) |
| Multiple sclerosis | 0 (0.00) | 1 (0.02) | -0.02 (-0.07, 0.02) |
| Musculoskeletal and connective tissue disorders | 7 (0.09), (0.04, 0.19) | 5 (0.10), (0.03, 0.24) | 0.00 (-0.11, 0.12) |
| Arthritis | 2 (0.03) | 0 (0.00) | 0.03 (-0.01, 0.07) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 42 Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up)**
**Per Site Reported or Protocol Defined Criteria**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 30058 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 19892 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Polymyalgia rheumatica | 2 (0.03) | 1 (0.02) | 0.01 (-0.04, 0.06) |
| Rheumatoid arthritis | 2 (0.03) | 3 (0.06) | -0.04 (-0.12, 0.05) |
| Psoriatic arthropathy | 1 (0.01) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Arthritis reactive | 0 (0.00) | 1 (0.02) | -0.02 (-0.05, 0.02) |
| Skin and subcutaneous tissue disorders | 6 (0.08), (0.03, 0.17) | 2 (0.04), (0.00, 0.15) | 0.03 (-0.06, 0.12) |
| Alopecia areata | 2 (0.03) | 0 (0.00) | 0.02 (-0.01, 0.05) |
| Psoriasis | 2 (0.03) | 0 (0.00) | 0.02 (-0.01, 0.05) |
| Erythema nodosum | 1 (0.01) | 0 (0.00) | 0.01 (-0.01, 0.03) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t42.rtf. Generated from t_pimmc_sum_sub.sas 19JUL2021 12:55

**Table 42 Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up)**
**Per Site Reported or Protocol Defined Criteria**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 30058 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 19892 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Pemphigoid | 1 (0.01) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Lichen planus | 0 (0.00) | 1 (0.02) | -0.02 (-0.07, 0.02) |
| Lichenoid keratosis | 0 (0.00) | 1 (0.02) | -0.02 (-0.07, 0.02) |
| Endocrine disorders | 4 (0.05), (0.01, 0.14) | 1 (0.02), (0.00, 0.11) | 0.02 (-0.04, 0.09) |
| Basedow's disease | 2 (0.03) | 0 (0.00) | 0.02 (-0.01, 0.05) |
| Autoimmune thyroiditis | 1 (0.01) | 1 (0.02) | -0.01 (-0.06, 0.04) |
| Hyperthyroidism | 1 (0.01) | 0 (0.00) | 0.01 (-0.01, 0.03) |
| Eye disorders | 4 (0.05), (0.01, 0.14) | 1 (0.02), (0.00, 0.11) | 0.02 (-0.04, 0.09) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 42 Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up)**
**Per Site Reported or Protocol Defined Criteria**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 30058 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 19892 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Uveitis | 3 (0.04) | 1 (0.02) | 0.01 (-0.05, 0.07) |
| Iridocyclitis | 1 (0.01) | 0 (0.00) | 0.01 (-0.01, 0.03) |
| Blood and lymphatic system disorders | 2 (0.03), (0.00, 0.10) | 2 (0.04), (0.00, 0.15) | -0.01 (-0.08, 0.06) |
| Thrombocytopenia | 2 (0.03) | 2 (0.04) | -0.01 (-0.08, 0.06) |
| Gastrointestinal disorders | 2 (0.03), (0.00, 0.10) | 2 (0.04), (0.00, 0.15) | -0.02 (-0.08, 0.05) |
| Colitis ulcerative | 1 (0.01) | 0 (0.00) | 0.01 (-0.01, 0.03) |
| Crohn's disease | 1 (0.01) | 1 (0.02) | -0.01 (-0.05, 0.03) |
| Coeliac disease | 0 (0.00) | 1 (0.02) | -0.02 (-0.07, 0.02) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

File Name: t42.rtf. Generated from t_pimmc_sum_sub.sas 19JUL2021 12:55

**Table 42 Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up)**
**Per Site Reported or Protocol Defined Criteria**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 30058 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 19892 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Cardiac disorders | 1 (0.01), (0.00, 0.07) | 0 (0.00), (NA, 0.08) | 0.02 (-0.02, 0.05) |
| Myocarditis | 1 (0.01) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Injury, poisoning and procedural complications | 1 (0.01), (0.00, 0.07) | 0 (0.00), (NA, 0.08) | 0.02 (-0.02, 0.05) |
| Chillblains | 1 (0.01) | 0 (0.00) | 0.02 (-0.02, 0.05) |
| Investigations | 1 (0.01), (0.00, 0.07) | 0 (0.00), (NA, 0.08) | 0.01 (-0.01, 0.03) |
| Heparin-induced thrombocytopenia test | 1 (0.01) | 0 (0.00) | 0.01 (-0.01, 0.03) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t42.rtf. Generated from t_pimmc_sum_sub.sas 19JUL2021 12:55

**Table 46.1.1 Subgroup Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up) Per Site Reported or Protocol Defined Criteria by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 25282 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 16433 | Risk Difference (Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Total follow-up time (person-years) | 6337.9 | 4074.4 | |
| Average follow-up time (days) | 91.6 | 90.6 | |
| Median follow-up time (days) | 93 | 92 | |
| Any PIMMCs | 36 (0.57), (0.40, 0.79) | 16 (0.39), (0.22, 0.64) | 0.11 (-0.17, 0.39) |
| Nervous system disorders | 12 (0.19), (0.10, 0.33) | 6 (0.15), (0.05, 0.32) | 0.01 (-0.16, 0.17) |
| Seizure | 4 (0.06) | 3 (0.07) | -0.03 (-0.14, 0.08) |
| Neuropathy peripheral | 3 (0.05) | 0 (0.00) | 0.04 (-0.01, 0.09) |
| Central nervous system inflammation | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

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**Table 46.1.1 Subgroup Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up) Per Site Reported or Protocol Defined Criteria by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 25282 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Facial paralysis | 1 (0.02) | 1 (0.02) | -0.00 (-0.06, 0.06) |
| Hypoaesthesia | 1 (0.02) | 1 (0.02) | -0.01 (-0.08, 0.05) |
| Narcolepsy | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Peroneal nerve palsy | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Multiple sclerosis | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Skin and subcutaneous tissue disorders | 6 (0.09), (0.03, 0.21) | 2 (0.05), (0.01, 0.18) | 0.03 (-0.07, 0.14) |
| Alopecia areata | 2 (0.03) | 0 (0.00) | 0.03 (-0.01, 0.06) |
| Psoriasis | 2 (0.03) | 0 (0.00) | 0.03 (-0.01, 0.06) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

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**Table 46.1.1 Subgroup Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up) Per Site Reported or Protocol Defined Criteria by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 25282 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Erythema nodosum | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Pemphigoid | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |
| Lichen planus | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Lichenoid keratosis | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |
| Musculoskeletal and connective tissue disorders | 5 (0.08), (0.03, 0.18) | 3 (0.07), (0.02, 0.22) | 0.01 (-0.11, 0.13) |
| Arthritis | 2 (0.03) | 0 (0.00) | 0.03 (-0.01, 0.08) |
| Polymyalgia rheumatica | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |
| Psoriatic arthropathy | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.

MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).

File Name: t46_1_1.rtf. Generated from t_pimmc_sum_sub.sas 19JUL2021 12:55

**Table 46.1.1 Subgroup Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up) Per Site Reported or Protocol Defined Criteria by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 25282 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Rheumatoid arthritis | 1 (0.02) | 2 (0.05) | -0.04 (-0.13, 0.04) |
| Arthritis reactive | 0 (0.00) | 1 (0.02) | -0.02 (-0.06, 0.02) |
| Eye disorders | 4 (0.06), (0.02, 0.16) | 1 (0.02), (0.00, 0.14) | 0.03 (-0.05, 0.10) |
| Uveitis | 3 (0.05) | 1 (0.02) | 0.01 (-0.06, 0.08) |
| Iridocyclitis | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Endocrine disorders | 3 (0.05), (0.01, 0.14) | 1 (0.02), (0.00, 0.14) | 0.01 (-0.06, 0.08) |
| Autoimmune thyroiditis | 1 (0.02) | 1 (0.02) | -0.01 (-0.08, 0.05) |
| Basedow's disease | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 46.1.1 Subgroup Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up) Per Site Reported or Protocol Defined Criteria by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 25282 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Hyperthyroidism | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |
| Blood and lymphatic system disorders | 2 (0.03), (0.00, 0.11) | 1 (0.02), (0.00, 0.14) | 0.01 (-0.07, 0.08) |
| Thrombocytopenia | 2 (0.03) | 1 (0.02) | 0.01 (-0.07, 0.08) |
| Cardiac disorders | 1 (0.02), (0.00, 0.09) | 0 (0.00), (NA, 0.09) | 0.02 (-0.02, 0.06) |
| Myocarditis | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |
| Gastrointestinal disorders | 1 (0.02), (0.00, 0.09) | 2 (0.05), (0.01, 0.18) | -0.04 (-0.11, 0.04) |
| Crohn's disease | 1 (0.02) | 1 (0.02) | -0.01 (-0.06, 0.04) |
| Coeliac disease | 0 (0.00) | 1 (0.02) | -0.03 (-0.08, 0.03) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
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**Table 46.1.1 Subgroup Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up) Per Site Reported or Protocol Defined Criteria by Age (18-64 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 25282 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 16433 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Injury, poisoning and procedural complications | 1 (0.02), (0.00, 0.09) | 0 (0.00), (NA, 0.09) | 0.02 (-0.02, 0.06) |
| Chillblains | 1 (0.02) | 0 (0.00) | 0.02 (-0.02, 0.06) |
| Investigations | 1 (0.02), (0.00, 0.09) | 0 (0.00), (NA, 0.09) | 0.01 (-0.01, 0.04) |
| Heparin-induced thrombocytopenia test | 1 (0.02) | 0 (0.00) | 0.01 (-0.01, 0.04) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t46_1_1.rtf. Generated from t_pimmc_sum_sub.sas 19JUL2021 12:55

**Table 46.1.2 Subgroup Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up) Per Site Reported or Protocol Defined Criteria by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 4776 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 3459 | Risk Difference (Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Total follow-up time (person-years) | 1127.1 | 802.8 | |
| Average follow-up time (days) | 86.2 | 84.8 | |
| Median follow-up time (days) | 91 | 88 | |
| Any PIMMCs | 5 (0.44), (0.14, 1.04) | 5 (0.62), (0.20, 1.45) | -0.24 (-0.90, 0.42) |
| Musculoskeletal and connective tissue disorders | 2 (0.18), (0.02, 0.64) | 2 (0.25), (0.03, 0.90) | -0.04 (-0.44, 0.36) |
| Polymyalgia rheumatica | 1 (0.09) | 1 (0.12) | -0.04 (-0.30, 0.22) |
| Rheumatoid arthritis | 1 (0.09) | 1 (0.12) | -0.00 (-0.31, 0.30) |
| Endocrine disorders | 1 (0.09), (0.00, 0.49) | 0 (0.00), (NA, 0.46) | 0.07 (-0.07, 0.21) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t46_1_2.rtf. Generated from t_pimmc_sum_sub.sas 19JUL2021 12:55

**Table 46.1.2 Subgroup Summary of Event Rates of Potential Immune-Mediated Medical Conditions Reported During the Study (from Day 0 to End of Follow-up) Per Site Reported or Protocol Defined Criteria by Age (>= 65 Years)**

| System Organ Class<br>Preferred Term (# of Events) | Vaccine<br>(n, rate per 100 person-years, 95% CI)<br>N = 4776 | Placebo<br>(n, rate per 100 person-years, 95% CI)<br>N = 3459 | Risk Difference<br>(Vaccine - Placebo)<br>(rate per 100 person-years, 95% CI) |
|---|---|---|---|
| Basedow's disease | 1 (0.09) | 0 (0.00) | 0.07 (-0.07, 0.21) |
| Gastrointestinal disorders | 1 (0.09), (0.00, 0.49) | 0 (0.00), (NA, 0.46) | 0.07 (-0.07, 0.21) |
| Colitis ulcerative | 1 (0.09) | 0 (0.00) | 0.07 (-0.07, 0.21) |
| Nervous system disorders | 1 (0.09), (0.00, 0.49) | 2 (0.25), (0.03, 0.90) | -0.23 (-0.67, 0.21) |
| Neuralgia | 1 (0.09) | 0 (0.00) | 0.07 (-0.07, 0.21) |
| Neuropathy peripheral | 0 (0.00) | 2 (0.25) | -0.30 (-0.72, 0.12) |
| Blood and lymphatic system disorders | 0 (0.00), (NA, 0.33) | 1 (0.12), (0.00, 0.69) | -0.11 (-0.33, 0.11) |
| Thrombocytopenia | 0 (0.00) | 1 (0.12) | -0.11 (-0.33, 0.11) |

Note: Risk difference and its Confidence Intervals (CIs) are computed from Mantel-Haenszel Standardized Risk Estimates and 95% normal confidence limits with the stratification by study, while individual group statistics are not adjusted by strata.
MedDRA version: 23.0 (2019nCoV-101 Part 1, 2019nCoV-101 Part 2, and 2019nCoV-501) and 23.1 (2019nCoV-301 and 2019nCoV-302).
File Name: t46_1_2.rtf. Generated from t_pimmc_sum_sub.sas 19JUL2021 12:55